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Official Journal
of the
North Carolina
Medical Society
July 1992
Volume 53
Number 7

North Carolina Medical Journal

For Doctors and their Patients

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SPECIAL ISSUE:

Health and the Environment

**Managing
Environmental
Contaminants**

Ricky Langley, M.D., M.P.H., Guest Editor

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For Doctors and their Patients

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NORTH CAROLINA MEDICAL JOURNAL

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FOR DOCTORS AND THEIR PATIENTS

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On the cover: These four photos depict the methods many health care facilities use to convert potentially infectious medical material into harmless decontaminated waste. Photos courtesy Department of Environmental Safety, Duke University, Durham.

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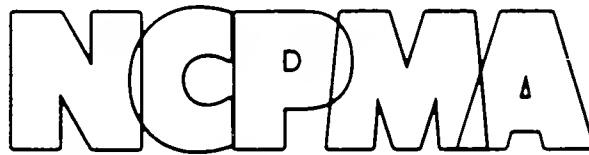
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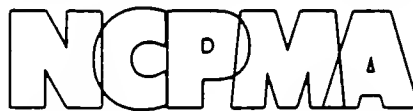


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Letters to the Editor

U.S. Health Care Dilemma

To the Editor:

When an article by Assad Meymandi, M.D., comes across my desk, I tend to read it. His perceptive and articulate abilities justify consideration of the statements in his article in the April issue (NC Med J 1992;53:153).

In this case, I feel compelled to express dissent. I agree with his description of the problems in our health care system. However, his proposal to eliminate private insurance companies is worrisome. From his article I infer that he would favor the government's becoming "one single payor." Theoretically, such a plan sounds sensible. In reality, if the private insurance industry were replaced by government, the frustrations that physicians feel in dealing with third payors would be further increased.

Decision-making and adaptations to changes in clinical medicine would become mired in bureaucracy and political posturing. Is there any government-run program not plagued by inefficiency and low productivity?

Rather than dismantling the insurance industry, let us seek effective reform. Regulations can be established so as to "level the playing field" for insurance companies. We would minimize the severe problems of "cherry picking" for more healthy patients and the exclusions for preexisting conditions.

The Health Insurance Association of America has proposed extensive regulations for health insurance policies to be offered to small business groups (JAMA 1991;265:3296-9). Similar proposals have been forthcoming from Blue Cross Blue Shield and by the National Association of Insurance Commissioners. A discussion of these concepts is in the *New England Journal of Medicine*, February 1992, pages 565-9.

Rather than encouraging government replacement of a private industry, let physicians strive for effective input into the steps needed to reform that industry. It can be done in the best interests of patients as well as physicians and could make major strides toward decreasing the problem with the uninsured persons in our country. We do need well-planned legislation and regulation from government, but with private industry functioning within an equitable framework.

Robert H. Bilbro, M.D.
Raleigh Medical Group, P.A.
3521 Haworth Drive
Raleigh, NC 27619

To the Editor:

Dr. Meymandi's essay, "U.S. Health Care Dilemma" (NC Med J 1992;53:153) is in itself a dilemma. He bemoans "our increasing health expenditures" and cites three bona fide reasons for escalating costs: malpractice premiums, space-age technology, and consumers' demand for expensive procedures.

Oddly, he accuses insurance companies for our health care crisis. He calls for the dismantlement of the insurance industry but fails to substantiate how the industry has so destroyed America's health care system. Since indemnity carriers and HMOs provide benefit coverage for health services, they are primarily responsible for providing patient access to physicians, and payment for their services. Dr. Meymandi's desire for their dismantlement smacks of biting the hand that feeds him.

The health insurance industry cannot be accused of adding exorbitantly to America's health costs. Rather, the industry doles out dollars for health care expenditures, which are driven ever higher by the three factors that Dr. Meymandi cites, not to mention this year's estimated

\$70 billion in fraudulent claims by physicians and hospitals to insurance carriers.

The reasons for America's health cost/access crises are many. There is much blame to go around and the health insurance industry must accept its share (e.g., through excessive administrative costs and the use of hassling utilization review techniques). But to call for the dismantlement of one part of the problem without recognizing the problematic contributions of others is to focus beyond the beam in the blamer's eye at the speck in the eye of the blamed.

Robert T. Harris, M.D., F.A.C.P.
Vice President, Medical Affairs
Carolina Physicians' Health Plan
P.O. Box 28125
Raleigh, NC 27611-8125

Lawyers' Ad

To the Editor:

It was with pain and disgust that I ran across the ad on page 211 of the May 1992 issue. If it has been the "enlightened" decision of the *Journal* to accept ads from these vultures of society, the scum who travel under the guise of "personal injury lawyers," please remove my name from the mailing list. If I determine that the decision to accept such dribbling trash for advertisement has been approved by the Medical Society, my resignation from that group will be shortly forthcoming.

John R. Miles, M.D.
Southeastern Specialist Clinic
825 Majestic Court, Suite F
Gastonia, NC 28054

To the Editor:

I was appalled when I discovered the "Ease the Pain" advertisement in the May 1992 issue. It is a sad day when our medical journal serves as an advertising medium for plaintiffs' attorneys. Cer-

tainly, any physician who has been through a malpractice suit can identify with the pain that we feel going through the process.

I am totally opposed to attorneys advertising in any medical publication, and I deem it as very inappropriate. I think most of my colleagues would agree with me. I hope that our advertising policy does not reflect this sort of lack of concern. If we need to sell this type of advertisement to publish a journal, then perhaps we should have a dues increase.

C. Ellis Fisher, M.D.
Gastonia Children's Clinic, P.A.
902 Cox Road, Suite C
Gastonia, NC 28054

To the Editor:

I, as well as many of my colleagues, have been astounded at the appearance of the full-page ad purchased by Smith, Debnam, Hibbert and Pahl in the May 1992 issue. Encouragement of litigation has never been and should never be considered as part of patient care. The ad implies that the physician should assist the patient in seeking retribution for physical and emotional pain.

I recommend that the *Journal* refund the full advertisement price to Smith, Debnam, Hibbert and Pahl. The editorial staff should also address the Medical Society in the next issue, regarding what I'm sure they realize has been a significant error in judgment.

I also recommend that the *Journal*, as a private non-subscription organ of the Medical Society, establish editorial guidelines that would prohibit advertisement that encourages litigation by a plaintiff attorney.

Kenneth J. Dols, M.D.
Southern Orthopaedics, P.A.
902 Cox Road, Suite D
Gastonia, NC 28054

To the Editor:

While I was reading the May 1992 issue, the ad on page 211 leaped off the page and grabbed me by the throat.

I think it's inappropriate to have plaintiff's lawyers advertise in the *Journal* when we all know a major proportion

of their attention is paid to malresults and turning those malresults into income for their law firms.

The masthead says a committee of the Editorial Board screens all local advertising before it is accepted. Was your committee asleep at the switch?

Edward McG. Hedgpeth, Jr., M.D.
Chair, NCMS Communications Cmte.
P.O. Box 27167
Raleigh, NC 27611

Reply from the Editors:

The editorial on page 262 of the June issue addresses your concerns. Smith, Debnam, Hibbert and Pahl submitted the following letter regarding its ad:

To the Editor:

It has come to our attention that our advertisement in the May issue of the *Journal* has raised concerns among some of the state's medical community. We apologize for any problems this ad might have caused; however, we feel we should respond to what has been a misinterpretation of our intention.

The purpose of our ad was to present our services in a professional manner to a highly educated audience. We sought to gain assistance from your readers to encourage clients to pursue sound legal advice for injuries suffered in a car accident, at the hands of a spouse, or at a work site. Patients come to their doctors not only to "get well," but also to seek advice. Our ad was *never* intended to urge patients to bring malpractice suits against their doctors.

We believe our is an over-litigious society. We do not advocate the pursuit of frivolous litigation. Furthermore, we view the filing of a lawsuit and "going to court" as a last resort after good faith efforts at resolution of a legitimate matter have failed.

As lawyers in the community, we view ourselves as serving several roles: counselors, problem-solvers, and, lastly, litigators. In personal injury cases our role is to assemble the facts, including medical data, and determine whether a

legitimate claim exists. Often we advise the client that "you have no case." With injury claims, we turn away more cases than we accept. However, we would not be fulfilling our professional duty if we did not assist those who have genuine personal injury claims, those whose lives have been turned upside down from the physical pain of their injuries and the emotional strain of dealing with insurance companies.

Our decision to advertise in the *North Carolina Medical Journal* demonstrates our support of the North Carolina Medical Society and our desire that the two professions work together to help individuals resolve issues impacting their lives. We regret that your readers may have perceived this to be otherwise.

John W. Narron
Section Head, Litigation Services
Smith Debnam Hibbert & Pahl
4700 New Bern Ave.
Raleigh, NC 27610

Cow Dung Cure

To the Editor:

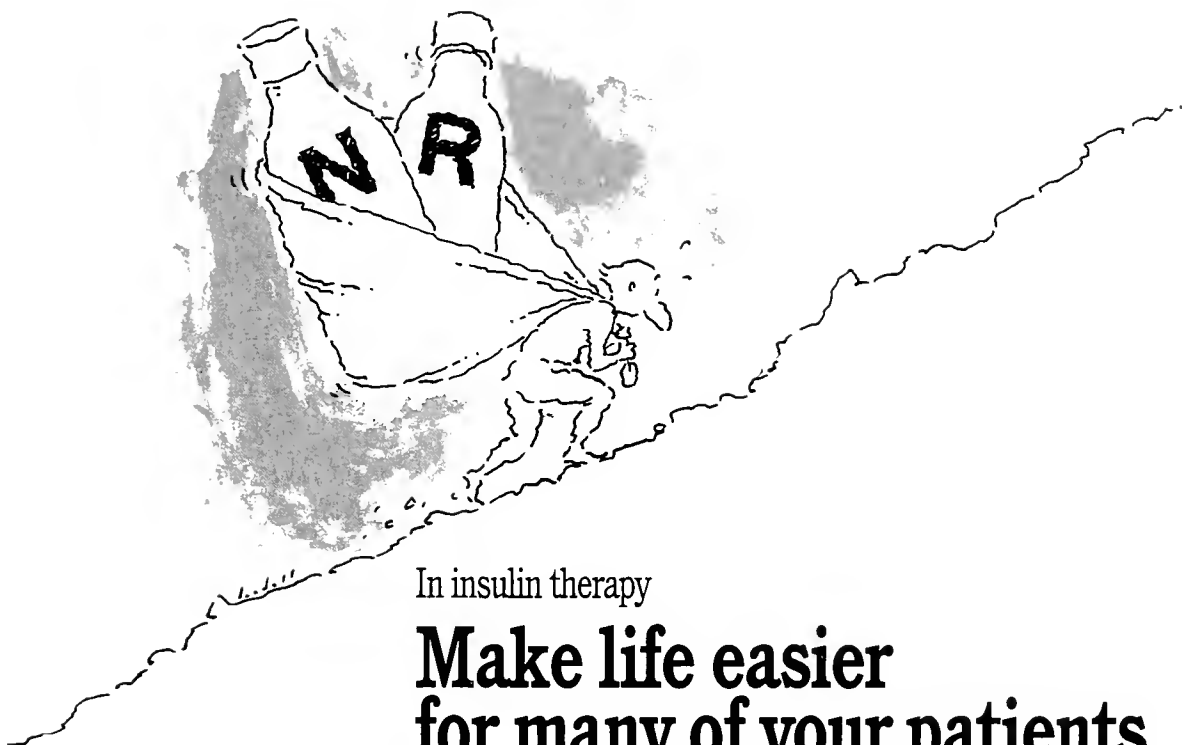
There is a gross error in Michelle Ritter's otherwise delightful article on southern folk medicine (NC Med J 1992;53;244-7). The cure for athlete's foot, stepping in fresh cow dung, is referred to as "medically unsound, but from a 20th-century perspective, absolutely ridiculous."

We called it "toe rot" when I was a barefooted child in the hills of Tennessee many decades ago. I have spent many hours with my ulcerous toe in a fresh, warm pile of cow dung. It never failed to cure. Today, I would prefer another treatment, more so since I have no access to cows, but I do have perfectly workable, reasonable healthy feet!

And, by the way, kerosene (we called it coal oil) is an excellent treatment for cuts and other minor wounds.

James L. Mathis, M.D.
Professor Emeritus
Dept. of Psychiatric Medicine
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Writing Resources

To the Editor:

Some years ago I received a little book from a colleague, *The Elements of Style*, by William Strunk, Jr., and E.B. White, 3rd Edition. I was greatly encouraged by this to write, even though my output has been minimal over the years. I can, however, recommend this "little book" to anyone who wants to try.

Recently another little book came to my house, this time from my father. I do remember that correctly! It is by Neville W. Goodman and Martin B. Edwards, and is called *Medical Writing: A Prescription For Clarity*. It is filled with useful and very careful help on clear writing. It is more directed to the scientific paper than Strunk and White. There are also some wonderful cartoons that give me both a chuckle and instruction.

For those of you out there who have ideas and want to write, get these two books. They are fun and instructional.

All of us at the NCMJ encourage all of you to do it! Put your thoughts, experiences, findings, and worries on paper. Send in your drafts. Ask questions. Let us all grow in wisdom shared, problems addressed, and fellowship increased.

I have long felt that growth in brotherhood with each other is one of the major reasons the NCMJ exists. No sexism is intended. If the editor can find a way out of this sticky wicket, please do so!

Margaret N. Harker, M.D.
NCMJ Editorial Board Member
P.O. Drawer 897
Morehead City, NC 28557

A Life-Saving Kit

To the Editor:

In the movie "My Girl," a child dies from an allergic reaction from an insect sting. In *Entertainment Today* the question is asked, "Would parents want their child to watch their Home Alone hero die a brutal death?" The producer responded that "kids are a lot smarter than we give them credit for. They know movies are not real life."

This is real life! Children can and do

die from allergic reactions. For many years I have been trying to educate the public about these life-threatening situations.

If the child in the movie had owned an insect sting kit, he would not have died. An important message would be to have parents educated on the necessity of an insect sting kit. More real, live children will die...education will save lives.

Claude A. Frazier, M.D.
4C Doctors Park
Asheville, NC 28801

A Response for Dr. Frazier:

Dr. Frazier has emphasized the importance of kits containing epinephrine in the treatment of allergic reactions to insect stings, in order to prevent complications and death.

Though rare, deaths in children from insect stings do occur. Children who have had systemic allergic reactions to stings, including generalized urticaria only, should have these kits available at all times—including at school.

I am concerned by how often patients, who have been treated in emergency rooms for systemic allergic reactions to stings, are sent home without prescriptions for kits containing epinephrine. I urge emergency room personnel to give these patients prescriptions for one of these kits (Epi Pen Jr., Epi Pen, ANA kit) and to show them how to use them. If they do not have the time to show them, please urge the patient to see their personal physician for a demonstration.

Hopefully, when patients allergic to insect stings see the movie "My Girl," they will see their personal physicians to review how to treat these reactions. These epinephrine-containing kits can be life-saving, and physicians must take the time to show patients how to use them.

J.A. Bardelas, M.D.
Adult & Child Allergy
100 Westwood Ave.
High Point, NC 27262

"Sweet Thing" Revisited

To the Editor:

The *Journal* has published two articles about my buddy, Sweet Thing. Sadly, Sweet Thing has disappeared. I

don't know what happened to him. Some people said, "He's on the prowl." No, he has been fixed. Every evening he goes out. He comes back inside around 11 p.m. and curls up beside me. I put my arm around him, and we both go to sleep. Sometimes during the night he will run across my back, letting me know he wants to eat and go outside. I do both, as any dutiful servant would do.

I fill his bowl with food, then I let him out. I leave the door open and go back to bed. He may stay outside about an hour. The police station in Biltmore Forest is next door to me. I call them up and ask them if they will check to see if Sweet Thing has come back inside; if so, would they please close the door. They have always been obliging to me.

Sweet Thing and I understand each other. A few nights ago, I was a bit depressed. He got up and put his nose against mine. He looked into my eyes and said with his expression, "What's wrong?"

I know when he's afraid. When he hears the door open, his pupils dilate and he comes to my side knowing I will protect him. I reassure him, then he lays back down.

I went to a movie the other night. I came in about 10 p.m. and let him come in. He wanted to go back out, which is his custom. I opened the door, leaving it open as I usually do. I awoke about 1 a.m. He hadn't come back in. I called his name—no response.

The next morning he hadn't returned. I cried. I prayed. I didn't feel like going to my office, but I went anyway. I called the police. They put a ladder up to look for him on my roof, but couldn't find him.

A miracle! At 11 p.m. there was a meow at the back door. It was Sweet Thing! It was raining, but he wasn't wet. Someone must have had him in their house. Was he glad to see me and vice versa. Now he sleeps beside me instead of at the foot of my bed. I think sleeping there makes him feel more secure. It sure makes me sleep better.

Claude A. Frazier, M.D.
4C Doctors Park
Asheville, NC 28801

LETTERS continued on page 335

Environmental Health

Should We Be Concerned?

Ricky L. Langley, M.D., M.P.H., Guest Editor

Dr. Ricky Langley has partaken of the wonderfully diverse educational opportunities offered in the State of North Carolina. He graduated from North Carolina State University and then Bowman Gray School of Medicine at Wake Forest University. After an internal medicine residency at Pitt County Memorial Hospital and East Carolina University, he undertook a fellowship in Occupational Medicine at Duke University and simultaneously earned a Master of Public Health degree from UNC-Chapel Hill. He is currently an assistant clinical professor in the Division of Occupational and Environmental Medicine in the Department of Family and Community Medicine at Duke University in Durham.



He is a member of the North Carolina Medical Society's Environmental Health Committee, a fellow of the American College of Preventive Medicine, the American College of Physicians, and the American College of Occupational and Environmental Medicine. He is also a member of Phi Kappa Phi, Sigma Xi, and the American Public Health Association, and is currently secretary-treasurer of the Carolinas Occupational Medical Association.

His research interests include agricultural medicine and the health concerns of health care workers. He has presented numerous lectures to professional and farm groups throughout the state. We are pleased that he accepted Dr. Stead's invitation to coordinate this special issue on Health and the Environment. —Ed.

Have you read the news lately? Hazardous waste spills on the highway! Global warming! Medical waste washes up on local beaches! Nuclear power plant shutdown! Ground water contamination found in local wells! Air quality index poor! These are just a few of the headlines we hear or read about daily. It is estimated that every citizen produces an average of 1,300 pounds of garbage per year. Nationally, this would fill a convoy of 10-ton garbage trucks 145,000 miles long.¹ Will we ever be able to control these increasing amounts of pollution? Will our lives be shortened due to exposure to environmental contamination? How can we advise our patients about the risks of living close to hazardous waste sites? How do we even know that a hazard exists? How do we investigate the potential problem and modify or remedy it? These are examples of the questions that physicians will deal with as the public becomes more aware of the hazards of a contaminated environment. Equally important is the question of what we physicians can do to control the various forms of pollution we create as part of our normal daily practice.

Until the AIDS epidemic, the focus of modern medicine had gradually shifted from dealing with acute infectious diseases toward issues of prevention and treatment of chronic health problems. We increasingly recognize environmental agents as contributors to chronic illness. For example, exposure to toxic agents at work and in the environment may be responsible for 6% to 13% of all cancer deaths.² Unfortunately, our knowledge of the hazards associated with environmental contamination by chemical and physical agents has not kept up with the introduction of new industrial products. Hundreds of new chemical agents are developed each year. Occasionally they are accidentally or intentionally discharged into the environment, but their long-term health effects on humans and wildlife are often unknown.

Some agents that have been around for thousands of years are proving more hazardous than we had thought. For example, lead poisoning is now described as the number one environmental health hazard of young children.³ The Centers for

Disease Control recently lowered the level of recommended exposure because of new evidence about mental retardation in children exposed to lead.⁴ Physicians need to ask patients about exposure to lead in hobbies such as the renovation of old houses or the use of lead-based paints or glazes in making pottery.

Fortunately, the removal of lead from gasoline has decreased air lead levels, but we must remember that excessive lead contamination is still a problem today, largely because of lead in peeling paint and lead-contaminated soil. It has been estimated that in North Carolina more than 8,000 children less than six years old have elevated blood lead levels (see Brewer, et al: The prevention of childhood lead poisoning in North Carolina. *NC Med J* 1992;53:149-52).

A concern in the field of environmental medicine is the potential conflict of viewpoints between academia, industry, and the public. Academicians often base their estimates of risk on extrapolations from animal data. Often there is disagreement about interpretation of such data, even among well-qualified academicians, and the public becomes confused about whom to trust. And not only the public, but physicians, too, have difficulty in understanding what "an extrapolated risk of cancer of 1×10^{-7} " actually means. Would such a risk be acceptable if a toxic waste site was being planned for your neighborhood? Even more troublesome, most toxic sites contain a mixture of agents, and we do not know the aggregate risk of the mixture. Without explaining the problems and risks in terms easily understandable to the public, mass hysteria may occur.

In addition, the public may be persuaded by individuals who claim that chemicals cause all sorts of "allergies" and other health problems even when no scientific studies support these statements. The media sometimes spread inflammatory statements that have little basis in fact, but this is frequently the only source of information for many people.

Industry may distrust academic physicians, fearing that they will attribute a medical problem to exposure in the employee's workplace, even though the problem is not clearly work related. Also, industry may feel that the public overestimates and overreacts to industrial waste discharges, failing to realize the economic benefits that industry brings to the community. For their part, the general public and some academicians frequently feel industry is only interested in profits, not the health of people in the surrounding community. With all this mistrust, where can one turn for help?

About This Special Issue

Unfortunately, most medical schools devote few, if any, hours to training in occupational and environmental medicine.⁵ Therefore, few physicians have any experience in evaluating patient complaints relating to the worksite or the environment. It is because of this need that the *North Carolina Medical Journal* is devoting this issue to a discussion of environmental health hazards.

On the bright side, North Carolina is blessed in having many individuals with expertise in environmental health. The U.S. Environmental Protection Agency (EPA) and the National Institute for Environmental Health Sciences are located in Research Triangle Park. Most of our major universities have scientists doing research on the environment. In selecting papers for this issue, I have chosen authors from academia, from public health, and from industry to cover various environmental issues of concern to citizens of North Carolina. I have personally worked with many of these talented individuals and would like to express my appreciation to every author that contributed to this issue.

Dr. James Tenney is director of the Buncombe County Health Department in Asheville and chairman of the Environmental Health Committee of the North Carolina Medical Society. He provides an excellent overview of environmental health hazards. Subsequent articles explore in further detail topics introduced by Dr. Tenney. Where possible, the nature of the problem in North Carolina is discussed.

Dr. Trenton Davis is professor of environmental health at East Carolina University. He is a former president of the National Environmental Health Association and has served as a member of the North Carolina Hazardous Waste Management Commission. In 1987 and 1988, North Carolina ranked 14th nationally for the amount of toxic chemicals released into the environment.⁷ Dr. Davis explains what hazardous waste actually consists of, the extent of the problem, and the difficulty managing hazardous waste in North Carolina. We can decrease the amount of waste generated in our daily practices by reducing, recycling, and reusing products and by encouraging the manufacturers of medical supplies to similarly do so.

Drs. Jerry Tulis and Wayne Thomann of the Division of Occupational and Environmental Medicine at Duke University discuss medical waste. Both have national reputations in bio-hazards and environmental health management in academic facilities. They provide a brief overview of microbiological agents and their role in the pathogenicity of medical waste and explain the threat that may exist to the public. Proper handling and disposal of medical waste generated in the office is essential and may be enforced under threat of fines and penalties in the near future.

Dr. William Meggs, an allergist/immunologist at East Carolina University, discusses indoor air pollution. He served on a National Academy of Science subcommittee on immunotoxicology and is investigating individuals with multiple chemical sensitivity and environmental allergies. Numerous medical conditions have been associated with poor indoor air quality.⁸ Dr. Meggs discusses some of the agents involved and methods used to investigate complaints associated with the indoor environment.

Dr. James Watson is a professor in the School of Public Health at UNC-Chapel Hill. He is a former president of the Health Physics Society and has done extensive research on radon in North Carolina. Radon is reported to be the second

leading identifiable cause of lung cancer in the U.S.⁶ When taking a health history, how many physicians ask their patients whether home radon levels have been measured? Dr. Watson explains the sources of radon, methods of measurement, and suggestions for correcting high levels.

Is our water safe to drink? Dr. David Moreau, director of the University of North Carolina Water Resources Research Institute at North Carolina State University, discusses water quality standards in North Carolina, the extent of water pollution in North Carolina, and efforts to improve water quality.

Drs. Dennis Darcey and Linda Frazier, faculty members of the Division of Occupational and Environmental Medicine at Duke University, discuss food safety issues: What are the risks from synthetic pesticides and hormones in our food supply? Is irradiated food safe to eat? How can we increase the world's food supply without adversely affecting the environment?

Dr. Gwendolyn Powell is director of Occupational Health Services for Glaxo, Inc. Of the issues in environmental contamination, determination of actual risk is the most difficult. Science, economics, and politics are intertwined in the field of risk assessment and management. Dr. Powell explains how one evaluates the hazards posed by an environmental contaminant and how risks are determined.

I can foresee in the near future an environmental assessment of each newly built home. Buyers will know the radon levels in air and water; the chemical content of the drinking water; the fiberglass and asbestos content of tiles and insulation inside the home; the types and amounts of pesticides applied to the property; and the distances to the nearest landfills and industrial discharge sources. Curbside recycling will be mandatory. Movement in these directions is already occurring. The EPA has stated its goal of using source reduction and recycling to divert 25% of the nation's municipal solid waste from landfills and combustors by 1992.¹

Recommendations on the best ways to reduce pollution must be based on sound science. We must begin to clear up hazardous waste sites at a more rapid pace. Stiff penalties must

be enforced on polluters. We must explain hazards and benefits to the public in terms they will understand. Unfortunately, a single issue of the *Journal* cannot adequately cover all topics of environmental health. I hope that in the future we can address topics such as outdoor air pollution, electromagnetic radiation, noise pollution, and pests and pesticides.

Yes, we must be concerned about the health of our environment. Environmental education should begin at an early age. Parents and teachers as well as employees and employers must take an active role in this education process. Decisions and actions we take today to reduce pollution will not only affect our health but that of future generations as well. □

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Environmental Hazards And Health Risks

A Public Health Viewpoint*

James B. Tenney, M.D., Dr.P.H.

Here in North Carolina the balancing influences that affect life, health, disease, injury, and death have combined their effects so that the average life expectancy for state residents has increased by more than half since the turn of the 20th century. Why then do physicians and public health leaders appear concerned about environmental health risks? Why do we hear about them from special interest groups and politicians in daily papers, on radio newscasts, and on television shows? What are environmental hazards and health risks, anyway?

Environment, Hazards, and Risks

Simply stated, environment means surroundings—features and forces outside the human body that affect a person, whether or not he or she can sense them. Air, soil, light, sound, water, and food are parts of the environment. Features or forces that contribute to human death, disease, disability, and discomfort are called environmental hazards. The probability that such a hazard will actually cause the harm it is capable of is called its environmental health risk. Significant environmental hazards may represent slight environmental health risks.

The variety and number of environmental hazards and their associated health risks change over time. They expand as the population increases, as research reveals previously unrecognized exposures, and as technology produces new substances or new combinations of old ones. People are less likely to contract typhoid fever because public water supplies are treated, but they are more likely to be injured from lightning strikes because the population density has grown.¹

Hundreds of new chemicals are marketed annually and thousands are in regular use.² Newly recognized hazards and increased risks make news, while safety and abatement are often unnoticed. Virtually anything in the environment is a potential hazard, in the sense that green apples can poison and pure water can drown, but the term "environmental hazards" usually refers to substances suspected as pollutants or contaminants in air, water, or food—the most common pathways for human exposure. Other "hazards" are taken for granted, or regarded as background.

Risk Assessment

Health risk assessment is the process of estimating the chances, expressed as the

probability, that a certain health effect will be realized under particular circumstances (see article on risk assessment on page 377). Risk assessment is always difficult and often imprecise, but important and necessary if policy makers and the public are to benefit from our best professional judgment. It is essential for good decisions about environmental education, regulation, change, or control. Problems arise when too little is known about the environmental hazard in question or the exposure that may be experienced. Because risk assessment is a technical art, full of assumptions about missing data, we should not be surprised that we sometimes have great problems in communicating risk assessment information to policy makers and the public in ways they can use and understand.

Pathways of Exposure

Human exposure to environmental hazards occurs chiefly through three final common pathways by which hazardous substances enter the body: air, water, and food. Indoor and outdoor air contain contaminants that can enter through the respiratory tract; water and food contaminants can enter through the intestinal tract. Injection, direct contact, and absorption

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through the skin are less common pathways. Some environmental hazards follow more than one pathway of exposure. Usually people do not recognize hazardous contaminants, or they would try to avoid them. Strangely, avoidance does not seem to extend to such recognized hazards as tobacco products, alcoholic beverages, or dietary fat.

Air

Outdoor air is cleaner and safer to breathe today than it has been for years, at least with respect to "killer" fogs, smog, and classic air pollution.³ In North Carolina's cities, stricter governmental regulations, lead-free automobile fuel, lessened exhaust emissions, and fewer smokestack industries have combined to reduce outdoor environmental hazards. Known hazards (those airborne specks of matter called particulates, lead, sulfur dioxide, carbon monoxide, and others) are monitored by official agencies and controlled by producers. They are generally maintained at lower levels today than the public recognized by sight and smell 20 years ago. Ozone and nitrogen dioxide have apparently increased in some areas, and occasionally reach levels that may produce respiratory irritation in some sensitive persons. Overall, the substances we usually think of as causing air pollution do not present much health risk for most of the population.

However the outdoor "greenhouse gases"—carbon dioxide, nitrous oxide, methane, and chlorofluorocarbons (CFCs)—have increased. They principally result from human activities and population growth and contribute to the environmental hazard of global warming. CFCs reduce the desirable layer of ozone in the distant stratosphere, allowing sunlight to warm the greenhouse gases in the immediate atmosphere, where undesirable ozone is created and heat is retained. Higher average global temperatures may make summer heat waves stronger, melt polar ice, extend ocean and desert areas, and change the pattern of certain human diseases. Immediate health effects in-

clude more heat-related deaths and skin cancers; possible long-term effects include more infectious diseases and less available food supplies for the growing population. Global warming poses more health risks to the population than any exposures to regulated nuclear plants, hazardous waste sites, modern municipal incinerators, or waste management facilities.^{4,5} Some global warming has already been observed, and efforts are now underway to reduce CFC emissions.

Indoor air now represents a greater environmental hazard than outdoor air. The ordinary home atmosphere contains many different contaminants, and we must remember that the most sensitive individuals (the very young, the old, the chronically ill) spend the most time there. The workplace is another source of indoor air contaminants, sometimes at higher concentrations than in the home. Among the thousands of substances that may contaminate indoor air are radon, combustion products, organic gases, biological agents, minerals, and metals.

Radon is a colorless, odorless gas that occurs naturally from radioactive decay of uranium in soil and rock. It enters buildings through cracks in cement, floor drains, and other openings; concentrations build up if not exhausted by ventilation (see article on radon on page 361). Radon gives off radioactive particles that are breathed into the lungs and may induce cancer, especially in smokers. The gas is second only to smoking as a cause of lung cancer, and may cause or contribute to more than one in seven of all current cases.⁶ Radon's health risk is related to human exposure based on concentration of the gas and length of time it is breathed, modified by individual factors, particularly smoking. Simple steps can usually be taken to reduce concentrations that are higher than recommended. Radiation from x-rays, medical applications, and video display terminals does not exceed background levels and does not produce hazardous indoor air exposures.

Combustion products come from environmental tobacco smoke, wood smoke, and incomplete burning of gas or

kerosene in defective or unvented furnaces, stoves, and heaters. Particulates, carbon monoxide, nitrogen dioxide, and organic gases are among the hazardous substances that result. Particulates may cause eye, nose, and throat irritation, and they have been linked with respiratory infections, especially in young children of parents who smoke. Carbon monoxide may cause headache, fatigue, dizziness, and confusion. Nitrogen dioxide may irritate mucous membranes and possibly damage lung function. Avoiding smoke, assuring good ventilation, and maintaining heating appliances properly can greatly reduce health risks from combustion products.

Organic gases include a wide variety of substances derived from sources the average householder or office worker might never suspect. These sources include building construction materials, cleaning products, paints and solvents, hobby supplies, stored fuels, insect and pest controls, glues and waxes, dry-cleaned clothes, air fresheners and deodorizers, and even hot showers.

The concentrations of many organic gases are regulated in the workplace, but even low concentrations breathed for prolonged periods may affect long-term health. Acute health effects of organic gases include eye, nose, and throat irritation, headache, fatigue, memory loss, nausea, and difficulty breathing. Brief low concentrations or combinations of formaldehyde, benzene, chloroform, and others may sensitize some individuals; in high concentrations these substances may cause later lung problems, liver damage, or cancer.

Organic gases are common in the indoor environment where their health risks are hard to estimate, since traces of these hazardous substances are found in many apparently normal adults as a result of continuing background exposures. Even carbon dioxide, a product of people's breathing, can build up in crowded or unventilated spaces to levels that produce headaches and sleepiness for the occupants.

Biological agents may present risks of infection (bacteria, viruses, and fungi)

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OXYCODONE	XX	XX	XX	XX	XX

Blank space indicates that no such activity has been reported. Table adapted from Facts and Comparisons 1991 and Catalano RB. The medical approach to management of pain caused by cancer. *Semin. Oncol.* 1975; 2: 379-92 and Reuter JB, et. al. The chronic pain syndrome: misconceptions and management. *Ann. Intern. Med.* 1980 588-96.

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Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries. **Acute Abdominal Conditions:** The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions. **PRECAUTIONS:** **Special Risk Patients:** VICODIN/VICODIN ES Tablets should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. **Drug Interactions:** Patients receiving other narcotic analgesics, antipsychotics, anxiolytic agents, or other CNS depressants (including alcohol) concomitantly with VICODIN/VICODIN ES Tablets may exhibit an additive CNS depression. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus. **Usage in Pregnancy:** Teratogenic Effects: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN/VICODIN ES Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic Effects:** Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. **Labor and Delivery:** Administration of VICODIN/VICODIN ES Tablets to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from VICODIN/VICODIN ES Tablets, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness in children have not been established. **ADVERSE REACTIONS:** The most frequently observed adverse reactions include light-headedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include: **Central Nervous System:** Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence and mood changes. **Gastrointestinal System:** The antiemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur (see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of VICODIN/VICODIN ES Tablets may produce constipation. **Genitourinary System:** Urinary retention has been reported. **Respiratory Depression:** Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated. **DRUG ABUSE AND DEPENDENCE:** VICODIN/VICODIN ES Tablets are subject to the Federal Controlled Substance Act (Schedule III). Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of narcotics, therefore, VICODIN/VICODIN ES Tablets should be prescribed and administered with caution. **OVERDOSAGE:** **Acetaminophen Signs and Symptoms:** In acute acetaminophen overdosage, dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma, and thrombocytopenia may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. **Hydrocodone Signs and Symptoms:** Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur.

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or allergic sensitization (pollen, animal dander and excretions, molds and mildew, house dust mites, and insect parts). Infectious agents may transmit diseases such as tuberculosis, influenza, and histoplasmosis. Allergens can set off reactions ranging from hay fever and hives to asthma attacks in hypersensitive individuals. Central cooling, air handling, and humidity control equipment can maintain and spread biological agents. Risk is highly individualized, so thorough cleaning, good ventilation, and moderate humidity are the best defenses.

Asbestos is a possible mineral contaminant of indoor air, particularly in older buildings where insulation on pipes and furnaces, coatings on walls, and ceiling or floor tiles become chipped, cracked, and flaked. Based on high-concentration occupational exposure, it is known that breathing microscopic asbestos fibers, especially by smokers, can produce lung scarring and cancer years later. Public concern over this possibility (with little reference to risk assessment information) has led to asbestos laws, to withdrawal of asbestos materials from production, and to the formation of governmental asbestos control agencies. Costly asbestos removal from many buildings, schools, and public places has been ordered in North Carolina and other states. Removal efforts increase asbestos health risk for construction and maintenance workers involved, and perhaps for the very citizens they aim to protect.⁷ This policy response is contrary to risk assessment advice that the probability of cancer from typical indoor air exposures to asbestos is very small, several thousand times less than the risk from occupational exposures and several hundred times less than the risk from more common environmental hazards.⁸

Lead and mercury are metals that may be vaporized or suspended in indoor air by such activities as electrical repairs with lead solder, sanding or burning off old lead-based paint, tracking in lead with outdoor dust, spills from broken thermometers, or the use of old latex wall paints containing mercury mold preventives. Indoor air exposure may be

reduced by avoiding hazardous material or methods and by generous ventilation where exposure must occur. Breathing these metals can cause serious health effects even at low air concentrations but, in general, the more likely hazardous exposure is from eating contaminated food and other substances.

Water

Popular concern centers on how water looks, tastes, and smells for drinking. Public supplies in North Carolina rate high against these standards and even higher against more stringent federal laws and state regulations (see article on water quality on page 368). However, all water supplies may be subject to hazardous contamination from the environment—even household water that seems harmless may present health risks.

Biological contaminants can produce widespread outbreaks of disease. Water treatment methods developed over the years have proven remarkably effective in preventing epidemics of bacterial dysentery, typhoid fever, and even viral infectious hepatitis. The recently recognized hazards from giardia and cryptosporidia parasites now require a combination of filtration and chlorine disinfection of water from surface sources; neither method alone is sufficient to control the risk. Users of public water supplies in North Carolina have little exposure and less health risk from biological agents in their drinking water. Users of non-public or private water supplies still need periodic water testing to gain the same confidence.

Chemical contaminants include nitrates, metals, and organic compounds that can enter water supplies from natural or man-made sources, or develop from the subsequent water treatment process itself. Nitrates from agricultural fertilizers, animal manure, or defective septic tanks may seep through soil to affect wells, springs, and other ground water sources. They can sometimes be fatal, particularly in infants, so health risks are highest for young rural or farm families,

who should test their water regularly if contamination is likely.

Metals in water may include lead from plumbing system pipes or fixtures, and arsenic deposited from airborne dust or fumes. Lead, absorbed at even very low concentrations by young children, infants, and fetuses can produce permanent nervous system damage, decreased intelligence, and learning disabilities. Hyperactivity and delinquent behavior may follow.⁹ Arsenic rarely reaches hazardous concentrations in drinking water, but may cause serious health effects following industrial or agricultural exposure. Other metals like iron and manganese can discolor drinking water and stain appliances, but exposure produces no health effects.

Organic compounds such as pesticides and vaporous chemicals can produce serious health effects at high concentration exposures. They may contaminate water from agricultural runoff, accidental leaks or spills, or improper disposal of industrial, chemical, and household products or wastes. Fuel leaking from underground storage tanks and seepage from solid or hazardous waste landfills may contribute in some cases. However, even long exposures to low concentrations of organic compounds in drinking water are not known to cause significant health effects. Strict regulations, constant monitoring, and ongoing research help to assure a very low risk, particularly from large public supplies.

Radon is a possible waterborne hazard that may cause more cancer deaths than all other drinking water contaminants combined.¹⁰ The gas enters water supplies from underground sources; it is bubbled off from surface waters and dispersed by water treatment processing. However, in North Carolina and certain other areas it may remain at high concentrations in well or spring water flowing to the tap where it can add to indoor air exposure as a result of showering, bathing, and dish- or clothes-washing activities. Testing for radon in indoor air will reveal its presence; if the air concentration is low, radon in the drinking water is unlikely to cause much risk.

Food

The food supply in the United States, including North Carolina, is among the safest in the world today (see article on food safety on page 372). Health risks from food are due to biological agents, natural toxins or poisons, and chemical agents. Biological agents represent the greatest risk. Millions of cases and thousands of deaths are caused by foodborne bacteria, viruses, fungi, and parasites.¹¹ Some diseases like dysentery are caused by microbes directly, others are caused by microbial toxins like aflatoxin.

Since food shipping, storage, handling, cooking, and serving practices affect the risks from food, the World Health Organization recommends "Ten Golden Rules for Safe Food Preparation:"¹²

- 1) Choose food processed for safety.
- 2) Cook food thoroughly.
- 3) Eat cooked food immediately.
- 4) Store cooked food carefully.
- 5) Reheat cooked food thoroughly.
- 6) Avoid contact between raw and cooked food.
- 7) Wash hands repeatedly.
- 8) Keep all kitchen surfaces clean.
- 9) Protect food from insects, rodents, and other animals.
- 10) Use pure water.

Natural toxins are produced by plants to protect themselves against fungi, insects and animals. Sometimes these toxins reach levels that cause severe health effects when eaten by humans.¹³ Every year many people eat mushrooms, some eat poisonous ones, and a few die. Certain fish are poisonous, or become so in the process of preparation for cooking. Char-broiling fat meat and frying or smoking meat products may produce cancer causing compounds. Possibly 30% to 60% of all cancer deaths are diet-related, and nearly 8% of those are due to natural toxins in food itself.¹¹

Heavy metals, pesticide residues, food additives, and certain organic compounds contribute considerably less to the health risk of food, but remain a prominent public if not professional concern. Lead, cadmium, and mercury are the major hazardous metals in food. Lead exposure results from eating food con-

taminated with dust and soil exposed to fumes from leaded gasoline combustion, or with chips of lead-based paint.

Cadmium is widely used for coloring, metal alloys, and batteries; it accumulates in the body so long-term, low-dose exposures can cause irreversible kidney damage, bone destruction, and possibly cancer. Leafy vegetables, rice, and oysters or other shellfish can concentrate the chemical from contaminated soil or water, and thus contribute to food exposures when they are eaten.

Mercury acts much like cadmium in the body and the environment; industrial and household use creates low amounts in air that settle on soil and surface waters, where metal dust and vapors are changed to a form that is concentrated by fish, which may then be eaten by people. Fish advisories can reduce such low-level exposures. Batteries and other products should be recycled to reduce the environmental pollution source.

Pesticides (insecticides, herbicides, fungicides, and rodenticides) are added to the environment to destroy undesirable organisms. They may contain heavy metals, arsenic, or organic compounds including several that have been linked to human cancer following high occupational exposure levels. The Food and Drug Administration and other agencies regulate pesticide residues on food; most foods have none, and less than 1% have more than permitted levels.¹¹ The pesticide contribution to cancer health risk is believed so small that it cannot be distinguished from background risks at this time. Washing fresh foods before use can reduce the risk even further.

Additives are chemicals introduced during food production, storage, processing, or packaging. The introduction may be intended (to improve quality or processing) or unintended (resulting from the methods used).¹⁴ Additives that are hazardous only at high concentrations or to hypersensitive individuals are highly regulated and do not create a health risk for the general population.

Polychlorinated biphenyls (PCBs) represent an unintended chemical additive. They are long-lasting organic compounds formerly used in electrical equip-

ment that have entered the environment through industrial wastes. Traces of PCBs are widespread in soil and water, are concentrated in the fat of animals or fish, and contaminate food made from them. Environmental PCB concentrations are low and have no health effects on humans who are exposed.¹⁵

Dioxins are another unintended, long-lasting chemical additive. They enter air and soil or water as industrial by-products or waste contaminants, where they accumulate and may become concentrated in plants and animals used for food. Some dioxins have been suspected of being hazardous to humans, but the only confirmed problem has been mild skin disorder after high concentration exposure; no cancer, birth defects, or other health effects have been found, although extensive research continues.¹⁶

What's To Be Done?

There really are environmental hazards and health risks in North Carolina, but neither are so notable or numerous as some advocates suggest. Hazards and risks as well as the rest of the environment here belong for the most part to the public, which shares responsibility for careful management. There may be more health risk today from misguided public fear of minor environmental hazards than from those hazards themselves. The risk comes from costly actions to correct minor hazards, taken without sound risk assessment advice, instead of using limited resources to manage major hazards that would make a real difference for the public's health.

So what's to be done to reduce health risks? Global warming suggests support for population control on the one hand and waste recycling, recovery, and reuse on the other. The radon hazard suggests homeowners should test indoor air to learn whether exposure problems exist or need correction. The presence of biological agents in food suggests support for education about good food-handling practices and enforcement of appropriate laws and regulations. Other hazards and risks will take more study. Should old housing be rehabilitated to reduce lead

poisoning? Should municipal water lines be extended to reduce nitrate poisoning in rural areas? There are many questions to consider and costs to be weighed against benefits for the entire population.

We all should take stock of our surroundings. Environmental hazards are best managed by prevention. People who suspect symptoms due to hazardous exposures should consult their physicians for help with diagnosis, treatment, and sorting out environmental from personal health problems. Environmental hazards or health risks in the community should be reported to local health departments. For further information about environmental hazards and health risks, readers should write to the North Carolina Department of Environment, Health, and Natural Resources, 512 N. Salisbury St., P.O. Box 27867, Raleigh, NC 27611 (919/733-4984) or to the Occupational and Environmental Medicine Resource Center, Duke Univ., Box 2914, Durham, NC 27710 (1-800/672-0066). □

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Informed Medical Consent

To the Editor:

In the May issue, Peter J. Rizzolo, M.D. ("Does a Demented Patient Lose the Right to Refuse Surgical Intervention?" *NC Med J*;53:213-216) wrote about informed medical consent. In the case reported, the patient refused surgery. The psychiatric consultant was unable to elicit any logic from the patient for his refusal despite a vascular surgical consultant contending that without amputation the patient would eventually die from gangrene. There was also difference of opinion between next-of-kin (who felt the patient should be forced to have surgery) and the nursing staff (who felt the opposite). The author was advised by the psychiatric consultant to let the next-of-kin make the final decision, but the next-of-kin felt uncomfortable in this role. The author then decided to confine treatment to non-surgical and comfort measures.

The ambiguity surrounding the patient's awareness of his situation coupled with the lack of consensus put Dr. Rizzolo into a dilemma. Guidelines that I have found useful to assess competence to give informed medical consent are by Appelbaum and Grisso ("Assessing Patients' Capacities to Consent to Treatment," *New Eng J of Med*, 1988; 319:1635-1638). They

contend that a patient is competent if he can communicate choices, understand information, appreciate the situation and its consequences, and manipulate information rationally. Since this patient was "not spontaneously communicative" and even resisted conservative measures, his competence to give informed medical consent was questionable using these guidelines.

Another route could have been to request a competence hearing. Some clinicians feel that this is an abrogation of a physician's responsibility. I disagree, since the article itself states that "the issue of competence is a legal question and is determined by the courts." This may have removed Dr. Rizzolo from the conflict between the next-of-kin and the nursing staff. In all fairness to the author, from my observation most physicians would not request a competence hearing if next-of-kin even tacitly agreed with a treatment plan. Especially when there is no next-of-kin available, a competency hearing can have the effect of removing the physician from this type of ethical and medico-legal dilemma.

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Hazardous Waste

A North Carolina Dilemma

Trenton G. Davis, Dr.P.H.

Hazardous Waste! The phrase conjures visions of impending disaster, of uncontrolled threats to the environment and human health, of government mismanagement, of irresponsible industries. A 1990 Roper Poll indicated that the public ranked active and abandoned hazardous waste sites as the two most serious environmental problems.¹ However, the Scientific Advisory Board of the U.S. Environmental Protection Agency (EPA) views criteria air pollutants, toxic air pollutants, radon, indoor air pollution, and drinking water contamination as greater risks to public health than hazardous waste.¹ In fact, the board's review and analysis of environmental risks (titled *Reducing Risk: Setting Priorities for Environmental Protection*) showed that many old assumptions are wrong. Many of the public's concerns (including hazardous waste) pose relatively small risks while big problems, like radon and climate change, are virtually ignored.

Nevertheless, the negative public attitude about hazardous waste has made it difficult for state and local governments to site its treatment, storage, and disposal facilities. In North Carolina the Hazardous Waste Management Commission lost one of the country's biggest battles in trying to site an incinerator and an accompanying residuals landfill and solvent recovery unit. The commission was

thwarted by more than 25 lawsuits, by opposition from citizens living near sites determined to be suitable, and by the Council of State, which voted in December 1990 against transferring state property on which to build the facility.

It is apparent that opposition to siting has gone beyond the Not-In-My Backyard (NIMBY) syndrome to a Not-On-Planet Earth (NOPE) syndrome in North Carolina and the nation!² The location of hazardous waste facilities will continue to be a contentious process in the future.

Despite opposition, however, we in North Carolina continue to produce hazardous waste; we must learn to manage it in an effective and efficient manner that will minimize threats to the public's health and to the environment. This will require that citizens be knowledgeable about the nature of the problem: where hazardous wastes are generated; what constitutes hazardous waste; the kinds of health threats posed by hazardous waste; the

statutory requirements for managing hazardous waste; and the role of citizens in properly managing hazardous waste. The state health director has noted that physicians generate significant amounts of hazardous medical waste and has emphasized that the medical community has a real stake in the safe management of these materials.³

Hazardous Waste Defined

Hazardous waste is generally considered to be the by-product of manufacturing processes, but hazardous wastes are also generated in every household. For example, leftover paint and furniture strippers, drain cleaner, and oven cleaners constitute hazardous waste.⁴

The EPA considers a waste to be hazardous if it has any of the characteristics shown in Table I.⁵ Waste is also

Table 1
Characteristics of hazardous wastes

Flammable	Easily combustible; e.g. paint wastes, certain degreasers, solvents.
Corrosive	Dissolves metals or other material; burns the skin; e.g., rust removers, acid or alkaline cleaning fluids, battery acid.
Reactive	Likely to explode or ignite on contact with water or other materials; e.g., cyanide plating wastes, bleaches, oxidizers.
Toxic	Causes illness or death when humans are exposed to certain amounts; e.g., heavy metals, pesticides.

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considered hazardous if it appears on any of four lists compiled by the EPA specifically because the materials listed exhibit one of the characteristics described in Table 1 or they contain one of a number of toxic constituents harmful to health and the environment. The EPA regulations list more than 400 items, including hazardous wastes derived from manufacturing processes and from the discarding of commercial chemical products.

Health Effects

Although many studies have been conducted to look at the health effects of exposure from hazardous waste facilities and sites,^{6,7} it is sometimes difficult to establish a clear relationship between exposure and health effects. In order to

monitor the potential public health problems associated with exposure to hazardous substances from waste sites and chemical spills, Congress created the Agency for Toxic Substances and Disease Registry (ATSDR) in 1980.⁸ In cooperation with the states and the EPA, the ATSDR maintains national registries of persons exposed to hazardous substances and any subsequent serious disease or illness. The registries are intended primarily for people whose exposure was associated with a Superfund site, but also tracks those whose exposure resulted from a national emergency activity, contaminated soil, food, or water not related to a dump site, or from an occupational exposure of Superfund relevance.

In April 1990, the EPA requested that the ATSDR evaluate complaints by former employees and their families, and

by area neighbors of the former Caldwell Systems, Inc., (CSI) incinerator in Lenoir.⁹ The incinerator, built in 1976, was the object of much controversy for a number of years (see Figure 1).

Initially owned and operated by Caldwell County to burn waste from the furniture industry, the incinerator was leased to CSI in mid-1977. CSI began to transport material from other states to Lenoir for incineration. Beginning as early as 1982 until the incinerator ceased operation in May 1988, U.S. Navy torpedo fuel (propylene glycol dinitrate and two stabilizers, 2-nitrodiphenylamine and dibutyl sebacate) made up 10% of the total material burned. Cyanide gas in concentrations of 10 to 1,000 ppm was also present in the waste fuel. Workers alleged that the torpedo fuel caused severe headaches, lightheadedness, and nausea

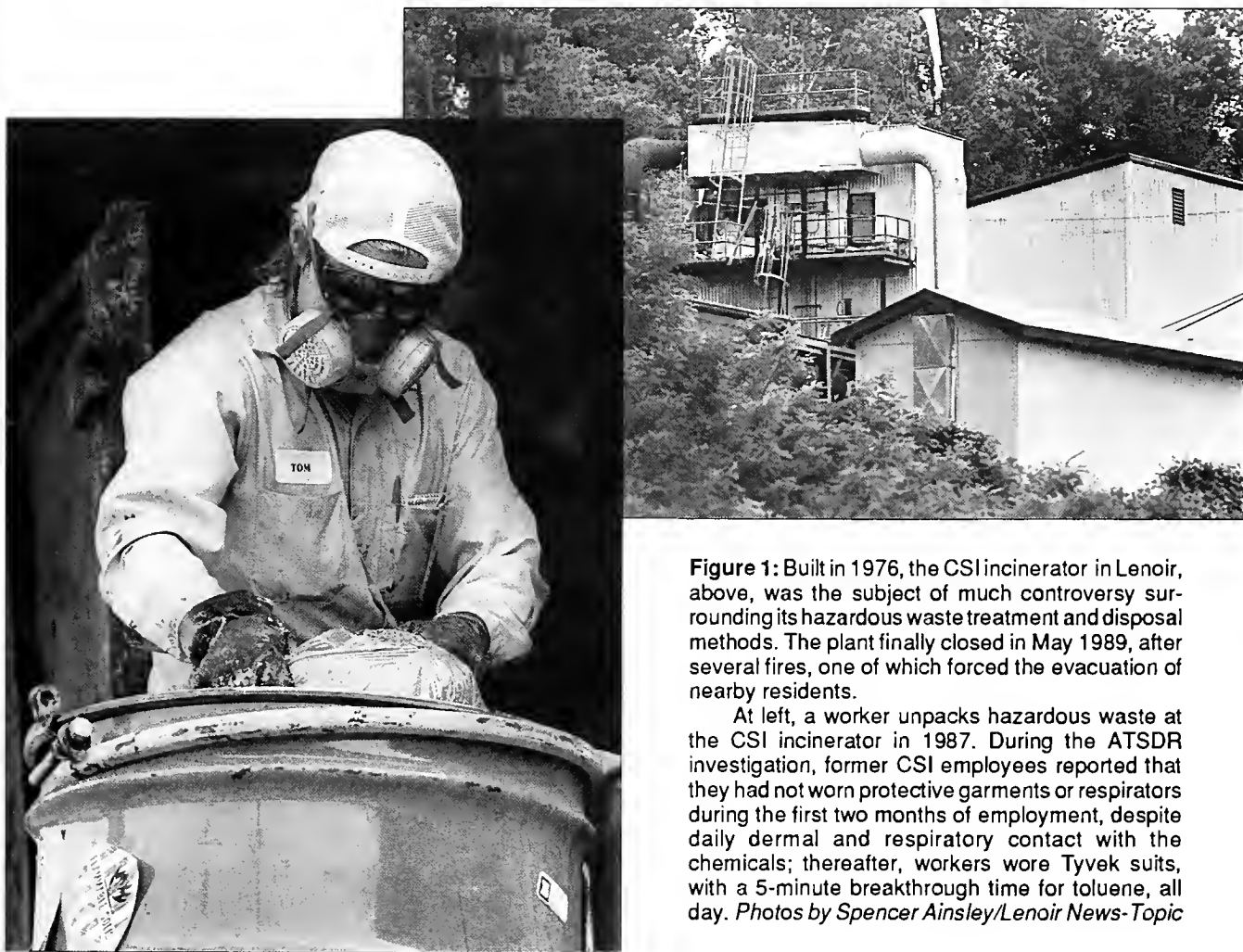


Figure 1: Built in 1976, the CSI incinerator in Lenoir, above, was the subject of much controversy surrounding its hazardous waste treatment and disposal methods. The plant finally closed in May 1989, after several fires, one of which forced the evacuation of nearby residents.

At left, a worker unpacks hazardous waste at the CSI incinerator in 1987. During the ATSDR investigation, former CSI employees reported that they had not worn protective garments or respirators during the first two months of employment, despite daily dermal and respiratory contact with the chemicals; thereafter, workers wore Tyvek suits, with a 5-minute breakthrough time for toluene, all day. *Photos by Spencer Ainsley/Lenoir News-Topic*

but, because workers were exposed to many chemicals mixed together, it was not possible for the ATSDR to blame the torpedo fuel or any single chemical for the reported health effects.⁹

The incinerator operated for the most part without any pollution control equipment, and the air quality regulations in effect during its operation were extremely limited. The Environmental Epidemiology Section of the North Carolina Department of Environment, Health, and Natural Resources (NCDEHNR) concluded that the facility and its operation did not represent state-of-the-art hazardous waste incineration capability.¹⁰ The plant finally closed in May 1989, after several fires, one of which forced the evacuation of nearby residents.

In July 1990, the ATSDR and the National Institute for Occupational Safety and Health surveyed local residents, including former CSI workers and their household contacts, to identify prevailing health concerns. Residents reported respiratory, arthritic, and allergic symptoms, as well as eye and airway irritation. Coughing, wheezing, and sputum production were the most common symptoms. Residents noted that the smoke and odor from the incinerator were worse at night.⁹

During the ATSDR investigation, former CSI employees reported daily dermal and respiratory contact with the chemicals. They also reported that no protective garments or respirators were provided for the first 60 days of employment; thereafter, Tyvek suits, with a 5-minute breakthrough time for toluene, were worn all day. The workers reported that they frequently waded in waste, and some cleaned out tank trucks without using respirators. Serious neurological problems consistent with toxic encephalopathy were reported by 14 workers. Four individuals who had extensive contact with solvents and waste torpedo fuel for periods ranging from 17 months to 3 years exhibited neurologic signs and symptoms. Contaminated work garments frequently were worn home to be laundered causing several workers to express concern about respiratory problems

among household members, especially children.⁹

The ATSDR sent a health advisory to the administrator of the EPA, warning of hazardous past work practices at CSI. Recommendations included further study of the extent of contamination and human exposure; restricted access to the facility and adjacent area; and follow-up activities at other sites anticipated to have similar problems, specifically, facilities handling the types of hazardous wastes burned at CSI. EPA and Occupational Safety and Health Administration investigators subsequently inspected 29 incinerators in other states, detecting a number of violations related to worker health and safety. As a result of the survey, investigators recommended changes in monitoring and additional training for facility operators.

Unquestionably there are occupational and environmental hazards associated with the operation of waste disposal facilities, but these are not unique even though they may be complex. Similar occupational hazards can be encountered in the workplace of a number of industries in North Carolina, and similar environmental hazards can be encountered as a consequence of emissions from a number of industries located within the state.¹⁰

The prevention of adverse effects to human populations and the environment from mismanagement of hazardous waste requires the education of employers and the public about potential hazards and risks, a commitment by all concerned to minimize hazards and risks, and the ability of state and federal agencies to regulate and evaluate this commitment through detailed inspections and monitoring.

Statutory Authority

The statutory authority empowering the EPA to regulate waste management and disposal practices derives from the Resource Conservation and Recovery Act (RCRA) passed by Congress in 1976. Congress was particularly concerned about the management of hazardous waste, because careless disposal had already led to the contamination of entire

neighborhoods and communities. For instance, Love Canal, a community near Niagara Falls, New York, was built on top of hazardous industrial wastes buried over a 25-year period. Chemical contamination of the land and ground water created fears of health effects from exposure and led to a government buy-out of homes and evacuation of the entire neighborhood (some of the homes can now be reoccupied).⁸

The RCRA requires that those who generate hazardous waste keep track of it. Generators must record the amounts and types of waste produced, including where and how it is stored or shipped and how it is finally disposed of. These records help assure that waste is disposed of properly in an approved facility and not dumped illegally. The original generator is responsible for assuring that there are no errors in the procedure along the way. Furthermore, generators of hazardous waste must be registered with the EPA. A generator cannot dispose of, ship, treat, receive, or store hazardous waste without being registered and assuring compliance with requirements for testing, classification, packaging, and reporting.

North Carolina is authorized by the EPA to enforce federal hazardous waste regulations. North Carolina requires that all businesses and industries that generate more than 2,200 pounds per month, and those that store, treat, or dispose of hazardous waste, submit annual reports of their hazardous waste activities. Based on these reports, a total of 224,339,359 pounds of hazardous waste was generated in 1990. This represents a 66% increase from 1989 to 1990,¹¹ most of which is attributed to an increase in waste generated from spills and other one-time events.

More than 74% of North Carolina's total waste was generated by the following industries: lumber and wood products, chemical and allied products, primary metal industries, fabricated metal products, electrical and electronic equipment, and rubber and plastic products. Nationally, the chemical industry is the largest generator followed by oil refiners.¹¹ Chatham was the top waste generating county in 1990 with a total of more than

Table 2
Top 10 generators of hazardous waste by county in 1990

Rank	County	No. of generators	Amt. generated(lbs.)
1	Chatham	3	73,079,230
2	Mecklenburg	73	24,273,804
3	Guilford	55	10,755,111
4	Wake	42	10,324,148
5	Stanly	7	9,010,773
6	Gaston	18	7,666,484
7	Pitt	6	7,172,843
8	Brunswick	4	6,002,040
9	Forsyth	27	6,002,040
10	New Hanover	15	4,149,842

Source: North Carolina Hazardous Waste: 1990 Report, NCDEHNR, August 1991.

73 million pounds of waste generated, followed by Mecklenburg, Guilford, Wake, Stanly, Gaston, Pitt, Brunswick, and Forsyth (Table 2).

Approximately 87% of the waste generated in the state during 1990 was shipped off-site for treatment, storage, or disposal. To the dismay of citizens and politicians in neighboring states, more than 182 million pounds of waste, or 89% of the total shipped off-site, was shipped to other states. The top waste receiving state was Louisiana followed by South Carolina, Alabama, Pennsylvania, and Virginia.¹¹ Incineration and landfilling were the methods used to handle the largest percentage of the waste (Table 3). It is encouraging to note that recycling technologies such as energy recovery, solvent recovery, and metal recovery were used to treat 22% of the waste shipped to other states.

In 1990, North Carolina received 49,115,664 pounds of waste from out-of-state, a 53% decrease from 1989. Alabama, Virginia, Pennsylvania, South Carolina, and New Jersey were the top five states that shipped waste here.¹¹ Within the state, waste treatment by means of energy recovery ranked as the most-used treatment method, followed by storage and solvent recovery. Overall, North Carolina is a net exporter of hazardous wastes, having shipped 133,511,727 pounds more to out-of-state facilities than was received from out-of-state in 1990!

The 1990 annual report does not

include waste generated by firms that produce less than 2,200 pounds per month. It is estimated that there are more than 4,000 such small-quantity generators in North Carolina,¹¹ including dry cleaners, photography labs, service stations, body shops, printers, laboratories and offices, building cleaning and maintenance companies, funeral parlors, motor freight terminals, and pesticide end users. Because of their number, they are difficult to regulate, but small-quantity generators cause many contamination problems (approximately 10% of the total national burden of hazardous waste comes from small-quantity generators⁸). Unfortunately, they often pay extraordinary disposal costs and frequently lack information on disposal options.¹² Nevertheless, although they do not submit reports, these small-quantity generators are required to manage their hazardous waste in accordance with federal and state rules and regulations.

Beginning in 1986 federal statutes have required reporting of toxic chemicals released into the air or water. Companies with 10 or more full-time employees, which have manufactured, processed, or otherwise used specified quantities of certain

toxic chemicals, must complete a toxic chemical release form, providing information on chemical emissions. The EPA makes this information available to the public through a nationwide computer database that provides citizens with information about chemical releases from businesses and industries located in their communities. In 1988, 136.8 million pounds of toxics were released by North Carolina industries—20.6 pounds for every man, woman, and child in the state.¹³ Louisiana led the nation with 175.6 pounds of toxics released for every citizen.

Cleaning Up Hazardous Waste Sites

In 1980, Congress passed the federal Comprehensive Environmental Response and Compensation Liability Act (CERCLA), commonly known as the Superfund. This law requires industry to pay for cleaning up the worst hazardous waste sites. Initial money to fund these cleanups came from a tax on industries that produce hazardous waste.⁸ Companies responsible for contamination are

Table 3
Methods used to handle North Carolina waste shipped to other states during 1990

Handling method	Total pounds
Incineration	81,211,971
Landfill	44,718,455
Energy recovery	18,320,300
Solvent recovery	14,485,025
Metal recovery	7,815,044
Physical treatment	6,065,035
Storage	3,802,716
Chemical treatment	3,645,192
Biological treatment	1,377,174
Other treatment/disposal	1,186,479
Grand total	182,627,391

Source: North Carolina Hazardous Waste: 1990 Report, NCDEHNR, August 1991.

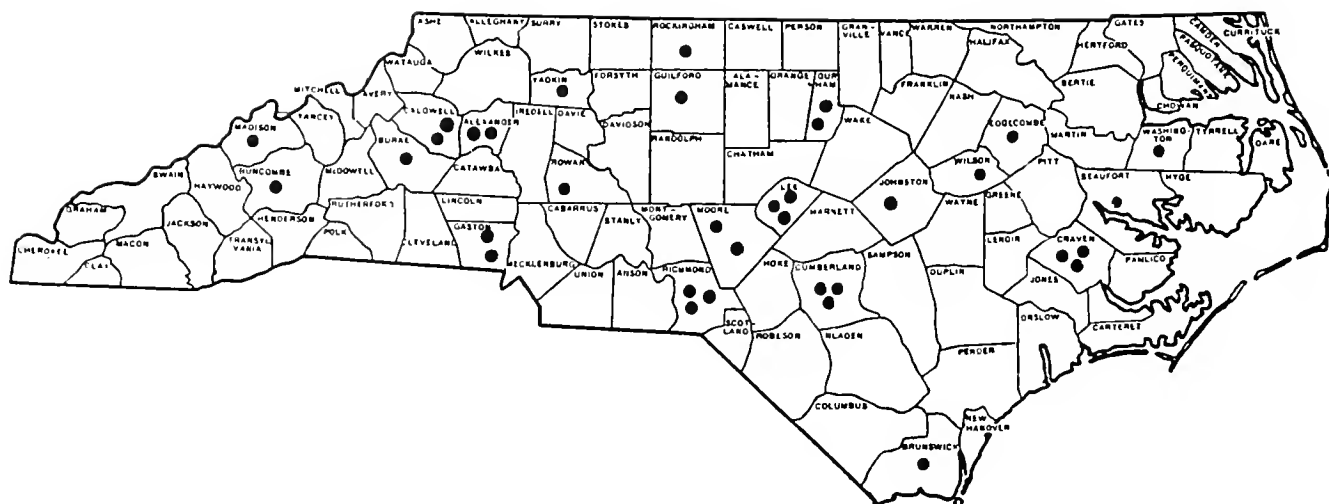


Figure 2: Hazardous waste sites in North Carolina listed in the EPA's National Priority List. Source: Superfund Section, Division of Solid Waste Management, NCDEHNR, Raleigh, 1991.

expected to repay the fund for cleanups performed under governmental authority. Contaminated sites may be recommended by the EPA or by the state environmental agency for placement on the Superfund's National Priorities List (NPL). Once on the list, Superfund money can be used for further studies or emergency cleanup work at the site.

Sites are ranked via a hazard rating system, using a variety of factors: ground water migration, surface water migration, soil exposure, and air migration. For each migration pathway, a variety of potential threats are evaluated: to drinking water, to the food chain, to sensitive ecosystems and biota, to water supplies, and to nearby human populations. Currently there are 1,207 sites on the NPL including 35 in North Carolina (Figure 2).

Evaluating and remediating a site can be extremely costly. For example, it took \$2.5 million of Superfund monies plus \$250,000 of state funds to clean up a deliberate spill along 240 miles of roadside in 14 central and eastern North Carolina counties. More than 42,000 cubic yards of soil contaminated with polychlorinated biphenyls (PCBs) were removed and subsequently buried in a specially-designed landfill in Warren County.

The choice of the Warren County site in 1982 was met with resistance from residents who claimed that the selection was made because the area was rural and predominately black.¹⁴

Since 1981, North Carolina has received more than \$8 million from the Superfund for evaluation and cleanup of state sites.¹⁵ Another \$12 million designated for cleanup of two NPL sites is in jeopardy because of the state's failure to provide a hazardous waste incinerator (a component of a regional agreement with Alabama, South Carolina, Kentucky, and Tennessee as to how they and North Carolina would manage their hazardous waste into the next century).

Altogether, the EPA has spent or obligated \$7.5 billion from the Superfund, and responsible parties have provided half again that amount. These billions of dollars have funded the cleanup of only 64 of the more than 1,200 NPL sites throughout the U.S.; work is in progress at 550 more sites.¹⁶ Over the next 30 years the Congressional Budget Office projects cleanup costs of at least \$150 billion. Cleanup costs at federal Superfund sites have averaged nearly \$21 million each.¹²

Sites that don't rank high enough to make the NPL are on the EPA's Corrective Action list. These sites may include a

minor spill or contamination or a very contaminated site located in an industrial area, far from residential areas and water sources. The EPA does not pay for these cleanups, but it does file a corrective action suit against the property owner, who must submit a cleanup plan. If the plan is approved, the EPA supervises the cleanup process. On occasion, a property owner is not able to pay for the cleanup. The EPA then tries to work out some kind of arrangement with the property owner so that the site can be remediated.⁸

Currently there are approximately 4,700 U.S. sites on the Corrective Action List. There are thousands of additional sites not on the NPL or the Corrective Action List, but designated for cleanup under state programs.⁸ In North Carolina, 824 such sites have been identified, located in practically every county.¹⁷

Even after a site is designated for cleanup, it may take many years before the process is completed. The site must be assessed, the property owner located, a cleanup plan developed and approved, and cleanup implemented. Federal and state laws, rules, and regulations are complicated, but they are intended to protect the public and the environment against threats posed by improper hazardous waste management.

Household Hazardous Waste

The average household contains approximately 100 pounds of hazardous waste.¹⁸ This stockpile is often the result of the homeowner's recognition that a product should not be put in the regular trash for disposal. But without an alternative disposal method, the material is stored in the home long after its usefulness has been exhausted or it is improperly disposed of: dumped on land, deposited into streams, discarded in municipal landfills, or poured down the drain. It is estimated that do-it-yourself oil changers improperly dispose of more than 180 million gallons of used motor oil each year! According to Scudder and Blehm,¹⁹ 70% of the residents of Larimer County, Colorado, were unaware of the potential environmental effects caused by improper disposal of hazardous household products. Most considered hazardous waste to be a problem of industry, manufacturing, and government.

Nationwide, more than 1.6 million tons of household hazardous waste (cleansers, automotive products, pesticides, paints, etc.) are generated each year. This represents about 1% of the municipal solid waste stream.¹⁸ Many communities have begun programs to collect hazardous household waste that is then properly managed by private contractors. Unfortunately, these programs are not available in all counties. Citizens must be educated about the risks associated with improper disposal of household hazardous waste, and that facilities and programs be provided for proper management of this category of waste.

Summary

North Carolina, along with the rest of the nation, faces a number of dilemmas regarding management of hazardous waste:

1. North Carolina businesses and industries generate a lot of hazardous waste, but the state lacks the capacity to manage it. For many, it has been acceptable to ship the waste to other states for treatment, storage, and disposal. Some of

the receiving states have indicated that they are no longer willing to serve as the "dumping ground" for North Carolina.

2. North Carolina, along with the EPA, has identified a number of hazardous waste sites now listed on the NPL. However, the state was excluded from its regional agreement with Alabama, South Carolina, Kentucky, and Tennessee in January 1991, meaning that Superfund monies may be withdrawn and that cleanup won't be completed at these sites.

3. Every year the country produces at least 260 million tons of hazardous waste—more than one ton for every man, woman, and child.⁷ Those opposed to constructing hazardous waste treatment facilities charge that businesses and industries should reduce their hazardous waste to zero or near zero, and they charge that the state is not doing enough to encourage waste reduction. North Carolina's hazardous waste regulations already require programs to minimize the amounts of waste generated by industries, but for most industrial processes, it is impossible to reduce the generation of waste to zero. However, industries must continue to reduce their waste through source reduction and recycling.

Hazardous waste and toxic materials do pose a risk to human health and the environment unless properly managed. Some authorities feel that the country is approaching a crisis point in dealing with the generation and disposal of hazardous waste. Only time will tell whether North Carolina can successfully meet the challenge and avert the crisis. □

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REMEMBER
1975?

JANUARY 1 H.R. HALDEMANN, JOHN C. MITCHELL AND JOHN D. EHRLICHMAN, FORMER TOP AIDES OF PRESIDENT RICHARD NIXON, ARE CONVICTED OF CONSPIRACY TO OBSTRUCT JUSTICE IN THE WATERGATE CASE. **FEBRUARY 11** MARGARET THATCHER IS ELECTED LEADER OF THE CONSERVATIVE PARTY, BECOMING THE FIRST WOMAN TO HEAD A BRITISH POLITICAL PARTY. **APRIL 30** THE SOUTH VIETNAMESE GOVERNMENT SURRENDERS TO THE COMMUNISTS, ENDING THE WAR IN VIETNAM. ♦ **SEPTEMBER 29** THE MALPRACTICE SITUATION IN NORTH CAROLINA REACHES A CRISIS AFTER THE LAST COMMERCIAL INSURANCE COMPANY ANNOUNCES IT WILL NO LONGER PROVIDE MALPRACTICE COVERAGE IN THE STATE. ♦ **OCTOBER 1** IN MANILA, MUHAMMED ALI DEFEATS JOE FRAZIER IN THE FIFTEENTH ROUND TO RETAIN THE WORLD HEAVY-WEIGHT BOXING TITLE. ♦ **OCTOBER 23** NORTH CAROLINA PHYSICIANS CREATE A MUTUAL INSURANCE COMPANY TO ASSURE A STABLE, FAIR PROFESSIONAL LIABILITY MARKET. ♦ THE YEAR'S TOP FILMS INCLUDE *JAWS*, *ONE FLEW OVER THE CUCKOO'S NEST*, AND *NASHVILLE*.

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Medical Waste Management

Federal Perspective and North Carolina Program

Jerry Tulis, Ph.D., and Wayne R. Thomann, Dr.P.H.

Congress defined "hazardous waste" as "a solid waste, or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may a) cause or significantly contribute to an increase in mortality or an increase in serious, irreversible, or incapacitating, reversible illness; or b) pose substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed." Congress thus concluded that the potentially infectious characteristics of waste presented a risk to the health and well-being of the American populace and therefore required regulatory action.

In December 1978, the U.S. Environmental Protection Agency (EPA) published its proposed regulations related to infectious waste in the *Federal Register*,¹ and in May 1980, it published the first phase of generic hazardous waste regulations. Between 1980 and 1982, the Administration and the EPA modified their approach to the management of infectious waste, publishing a *Draft Manual for Infectious Waste Management*² in September 1982. This guidance document was distributed widely and

critically reviewed by various professional organizations and individuals. In May 1986, the EPA finalized the 1982 document as *The Guide for Infectious Waste Management*. This document continues to represent the federal position on infectious waste management,³ and includes the statement establishing the Agency position on rule making: "while the Agency has evaluated management techniques for infectious waste, considerable evidence that these wastes cause harm to human health and the environment is needed to support federal rule making." But the Centers for Disease Control (CDC) concluded that "there is no epidemiologic evidence to suggest that most hospital waste is any more infective than residential waste. Moreover, there is no epidemiologic evidence that hospital waste has caused diseases in the community as a result of improper disposal."⁴ The absence of human infections resulting from exposure of the public to potentially infectious waste has been corroborated by the Agency for Toxic Substances and Disease Registry (ATSDR) in its report to Congress.⁵

Nevertheless, the washups of medical waste onto U.S. beaches during the spring and summer of 1988, prompted immediate action by Congress to eliminate this perceived threat to human health. The EPA promulgated the Medical Waste Tracking Act of 1988, a two-year demonstration bill affecting only New Jersey, New York, Connecticut, the District of Columbia, and Puerto Rico. Unfortu-

nately, much of the congressional dialogue leading to the passage of the bill was based on misinterpretation and misperception.⁶ Concurrently, Congress directed the ATSDR to conduct a risk assessment on the potential and real hazards of the infectious waste stream and to submit a report to Congress; the EPA was directed to submit a report on the health hazard assessment of medical waste by the end of 1991.

Infectious Waste, EPA Definition

Medical wastes include the following: isolation wastes, cultures and stocks of infectious agents and associated biologicals; human blood and blood products; pathological waste; contaminated sharps; contaminated animal carcasses; body parts and bedding; and a miscellaneous category that includes surgery and autopsy wastes, laboratory wastes, dialysis unit wastes, and contaminated equipment. The EPA defines infectious waste as that "capable of producing an infectious disease" and states further that "for a waste to be infectious, it must contain pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease." Treatment of infectious waste includes steam autoclaving, incineration, dry heat inactivation, gaseous exposure, chemical disinfection, and irradiation processes.

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It is not easy to categorize waste as infectious by the EPA definition. Identifying the presence in waste of a pathogen with sufficient virulence is a formidable task, even for trained professionals. Contaminating microorganisms can be isolated and identified, but the determination of pathogenicity and associated virulence is difficult. The resultant data may prove inconclusive because of the multiple factors necessary for induction of disease. Humans are an outbred population of peoples who vary in their resistance to infection. Numerous interrelated and independent factors govern and influence individual susceptibility to infection (age, sex, health, nutrition, chemotherapy, underlying disease, etc.), and these factors may change day-to-day. Attempting to establish the specific susceptibility to infection of those whose occupation involves the handling of potentially infectious waste is impossible. One is faced, therefore, with using a worst-case scenario—considering all medical waste to be contaminated with human pathogens of sufficient virulence and dose to infect the most resistant individual. This policy is akin to “universal precautions.”

Basics of Infectious Disease

Etiology

Knowledge of how microorganisms, the single-celled organisms that share some of the properties of the higher plant and animal kingdoms, cause disease and of how these infectious agents are transmitted is fundamental to a better understanding of the potential hazards associated with infectious waste streams. We must remember that microorganisms are ubiquitous in nature, and often found in large quantities and great diversity. Most microorganisms found in nature are harmless to man, animals, and plants, indeed their existence is required for the decay of vegetation, the digestion of food, for agriculture, and for numerous other beneficial purposes.

The species of microorganisms that are harmful to man, the human pathogens, includes viruses, rickettsia, bacteria, and fungi. They vary greatly in virulence; some are incapacitating and bothersome, such as the viruses causing the common cold; others are more serious and can prove lethal.

Bacteria can be placed into three distinct groups based on morphology: the various types of cocci or round microbes; the various rod-shaped or bacilliform microbes; and the corkscrew-shaped or spirilliform microbes. Numerous species of bacteria comprise the normal human

“The heightened concern about medical waste management is associated with public apprehension and fear of infection with the HIV...this concern is grossly overexaggerated and based primarily on perception rather than reality.”

flora; these organisms are usually harmless unless the host is compromised. We anticipate that medical waste, unless sterilized and handled aseptically, will be contaminated with various bacterial species, most of which are not human pathogens.

Rickettsiae are small coccobacilli, surviving primarily as intracellular parasites. Their host range is wide, including insects, birds, and mammals. Most human rickettsial diseases are transmitted by arthropod vectors (e.g., the “*Dermacentor andersoni*” tick transmits Rocky

Mountain spotted fever). However, some rickettsial agents are readily transmitted by aerosols (e.g., “*Coxiella burnetii*,” the causative agent of Q fever). In general, rickettsiae play an insignificant role in the infectiousness of medical waste.

Fungi include molds and yeasts. Most fungi are harmless to man, and many are needed for the production of enzymes, antibiotics, and foods, in addition to their important ecologic role in the decay of vegetation. However, there are pathogenic fungi that cause debilitating and incapacitating infections and serious life-threatening systemic diseases. The characteristic shape, consistency, and pigmentation of fungi grown on aciduric culture media are useful for presumptive identification. Although most fungi are saprophytic, living on dead and decaying matter, some of these can become opportunistic pathogens and cause serious diseases, especially in immunocompromised hosts.

The fungi are also implicated, as are some bacteria, in the causation of human allergic disease, such as when these organisms are dispersed in the indoor environment. On the whole, however, fungi do not play a significant role in the disease potential of medical waste.

Viruses represent an unusual assortment of organisms that are responsible for the majority of human diseases. They are extremely small in size, all possess either RNA or DNA as the genetic code, a protein coat or shell surrounding the nuclear material, and, most importantly, are obligate intracellular parasites. Upon infection of animal, plant, or bacterial host cells, the viral nucleic acid diverts the metabolic machinery of the host cell to the replication of viral progeny, ultimately liberating numerous infectious viral particles into the surrounding environment. The heightened concern about medical waste mismanagement (for example, beach wash-ups) is associated with public apprehension and fear of infection with the human immunodeficiency virus (HIV). As will be discussed later, this concern is grossly overexaggerated and based primarily on perception rather than reality.

Transmissibility

Diseases are classically transmitted via the respiratory route (inhalation), the oral route (ingestion), the contact route (casual or intimate), the parenteral route (including penetrating trauma or accidental needlestick), and through insect vectors such as mosquitoes, fleas, and ticks. Fortunately, most disease-producing microorganisms are fastidious and do not survive well in the environment.

The respiratory route is of extreme importance in the transmission of infectious microorganisms. Aerosolized particles able to penetrate the human respiratory tract and reach the deep alveolar spaces are identified as respirable particles; their size range of 0.5 to 5 microns includes all viruses, most bacteria, and many fungal spores. Human contagious diseases such as chicken pox, measles, influenza, and tuberculosis are readily transmitted from person to person via aerosols. The aerogenic route is the route most difficult to control; it truly represents a "silent hazard." Aerosols are insidious and can cause multiperson exposure by following air streams and contaminating remote areas. Antibody formation (i.e., seroconversion) of individuals after exposure is an important tool for confirmation of infection, especially with asymptomatic disease.

Penetrating trauma caused by accidental needlestick has been the primary cause of occupational infections with bloodborne pathogens. Approximately 90% of documented occupational HIV infections have been associated with sharps penetration,¹ primarily needlestick. Although needlesticks continue to present a risk to personnel involved in patient care and diagnostic procedures, the extensive improvements in the handling and disposal of sharps should significantly reduce the potential risk for the public.

Infectivity

In most instances, a single pathogenic microorganism is not sufficient to initiate infection; hundreds or thousands are required. Exceptions include tuberculosis and tularemia, where one bacterium can

initiate infection in a susceptible host. In addition, the infectious dose can vary significantly when the route of exposure is changed. Thus, the infectious dose for various species of microorganisms can range from a few cells or viral particles to more than a million, depending on the specific etiologic agent and the route of exposure. The infectious dose for many human pathogens is unknown, but some data are available from human studies and animal experiments. The infectious doses of HIV and hepatitis B virus (HBV) in the medical waste stream are not known, although data have demonstrated that

"The (state) advisory group proposed that the best method of protecting the public health was to emphasize special handling requirements that reduced the potentially infectious dose in the waste by adequate treatment or prevented exposure through protective packaging and secure storage."

patients infected with HBV have significantly higher bloodstream titers of virus than those infected with HIV (about 10 to 100 HIV/mL versus 10 million to 100 million HBV/mL). However, because viruses are obligate intracellular parasites, totally dependent on replication inside target mammalian cells, multiplication of these agents in the waste stream is virtually impossible. Viruses that may contaminate untreated waste blood and body fluids are subject to dilution and rapid loss of viability in the environment.

North Carolina Medical Waste Management

In response to increasing national pressures, North Carolina revised the state's infectious waste rules in early 1990 and assembled a Medical Waste Task Force to provide scientific, technical, and administrative advice. The primary objective of this group was the updating of state regulations to provide a high level of public protection and to assure that the rules were based on real risk rather than some perception of risk derived from the popular press. The advisory group proposed that the best method of protecting the public health was to emphasize special handling requirements that either reduced the potentially infectious dose in the waste by adequate treatment or prevented public exposure through protective packaging and secure storage. This proposal was based on the principles of disease transmission previously discussed and ultimately served as the primary focus around which the new rules were developed.

The first change was to abandon the designation "infectious waste" in favor of the more accurate "medical waste." Medical waste was defined as any solid waste generated in the diagnosis, treatment, or immunization of human beings or animals, or in the production or testing of biologicals. Within this broadly defined group of waste materials, a subset was identified that required special handling or processing. This subset was designated "regulated medical waste" and included categories of waste that posed a significant risk either to the public health or to the integrity of the solid waste landfill. The specific categories of medical wastes regulated in North Carolina are:

- 1) blood and body fluids in individual containers greater than 20 mL;
- 2) microbiological waste; and
- 3) pathological waste (bodies, body parts, organs, etc.). These wastes require special handling and decontamination prior to disposal in a sanitary landfill.

Special handling requirements were also defined for two other categories of medical waste, although they are not re-

medical waste, although they are not required to be decontaminated prior to disposal. Sharp objects must be placed in rigid, leakproof, puncture-resistant containers and handled in a manner that avoids human contact. Blood and body fluids in individual containers of 20 mL or less, such as blood sample tubes must be packaged in leakproof, protective containers to minimize potential public or environmental exposure.

The state rules also describe two levels of regulations for the storage, transportation, and treatment of regulated wastes depending on whether the material is managed on or off site. This stratification of requirements was established because of the uncertainty associated with the off-site management of untreated wastes. A recognized loss of control occurs with off-site transportation, storage, and treatment, and consequently, additional regulations were deemed appropriate. These emphasize careful tracking of materials that are shipped off site for treatment and define stringent operational requirements for facilities managing the decontamination of these wastes.

Discussion and Conclusions

The authors have devoted considerable effort during the past many years toward providing an appropriate and common-sense approach to the management of medical waste. During nationwide talks, several relevant issues have been promoted: a change in the descriptive terminology used by the EPA and others from "infectious" waste to "medical" waste; the complete lack of evidence for an infectious disease threat to the public sector from medical waste; the acknowledgement that a small number of occupational infections have occurred from the handling of medical waste; the greater possibility for introducing pathogens from household waste than from hospital waste; and the extremely remote probability that the public will become infected with either HBV or HIV from contaminated medical waste. Although it

is acknowledged that beach wash-ups are repulsive and aesthetically displeasing, infection resulting from exposure is highly unlikely.

The literal interpretation of the EPA definition of medical waste would exempt material whose burden of human pathogens was determined to be below the infectious dose for man, should this dose be known. The mere presence of human pathogens would not categorize the waste as infectious; it could contain significant levels of contaminating non-pathogenic microorganisms and human pathogens, if the levels were below the infectious dose for a susceptible individual by a prescribed route of exposure.

The ATSDR and the EPA calculate that the risk of infection in individuals who are not occupationally exposed is two orders of magnitude lower than workers' (i.e., 1/10 million vs 1/100,000 for HBV infection and 1/100 million vs 1/1 million for HIV infection). The exposure potential for the public is further reduced by one to two orders of magnitude by environmental factors such as organism die-off, dilution effects, and environmental stresses. Thus, the overall risk for the public is at least three to four orders of magnitude lower than for the worker, and even here risk assessments have been based primarily on infections resulting from patient care rather than from the handling of medical waste.

Factoring in these probabilities results in a calculated risk of infection to the public from HBV between 1/100 million and 1/1 billion, and from HIV between 1/1 billion and 1/10 billion! Any federal regulation of medical waste based on these probabilities of infection would be grossly inconsistent with the policy used by both the EPA and the Occupational Safety and Health Administration for occupational exposure to air toxics or carcinogens, where a probability for developing disease of 1/100,000 to 1/1 million is used as a regulatory guideline.

There is no documented evidence of infection of the public from medical waste; the extremely low probability of risk should mean that the public is safe from the potentially infectious nature of medi-

cal waste. If federal regulation is imposed, its purpose should be clearly stated as being aesthetic and aimed at reducing public outrage and perception, not at protecting the public from infectious diseases. In addition, the tremendous funds expended in unnecessary regulatory management and disposal practices could be diverted to the improvement of acknowledged health care problems. □

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Health Issues of the Young

YOUTH AND ALCOHOL



Which drug is the most often used and abused by young people? It may surprise you to learn that the drug is alcohol. Nationally about 5 million 14-17-year-olds in 1990 experi-

enced negative consequences (i.e., arrest, involvement in an accident, impaired health or impaired job performance) from using alcohol. A survey conducted by PRIDE (Parent Resource in Drug Education) showed that nationally about 100,000 kids ages 10 and 11 get drunk at least once a week. It is never too early to begin talking with your child about alcohol and the problems alcohol can cause. Let's take a look at some of the facts involving young people and alcohol:

Overview

- Use of alcohol, a "gateway" drug, usually precedes other drug use. A survey of 27,000 seventh to twelfth graders in New York state found little or no use of other drugs among teens who had not used alcohol first.
- Children of alcoholics have a four times greater risk of developing alcoholism than children of non-alcoholics.
- More than 800 children up to age 14 and more than 8,000 15-to-24-year-olds died in alcohol-related highway crashes in 1988.

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- More than half of the college students who confessed to committing violent crimes on or near campus said they were high on alcohol or drugs when they broke the law. Also, almost half of the victims of violent campus crimes said they were drinking or using other drugs when they were victimized.

Usage Patterns

- Although the use of alcohol is illegal for anyone under 21, it remains more widespread among youth than use of tobacco or any illicit drug. Among college students alcohol is more than twice as popular as both tobacco and marijuana, and almost nine times as popular as cocaine.
- Thirty-five percent of high school seniors, in one study, reported having five or more drinks in a row in the past two weeks. About 4% reported drinking daily; and nearly all (92%) had tried alcohol.
- In the '40s and '50s youths took their first drink at ages 13 and 14; today, they start at age 12.
- Virtually no use of alcohol, tobacco or illicit drugs (except cocaine) begins after age 25, research shows.
- Alcohol problems and bulimia (the binge-and-purge eating disorder) are linked in teenage girls, one survey found. High school girls who met four or more of the five criteria for bulimia had a significantly higher incidence of alcohol problems than girls who met less than four criteria.

Drinking and Driving

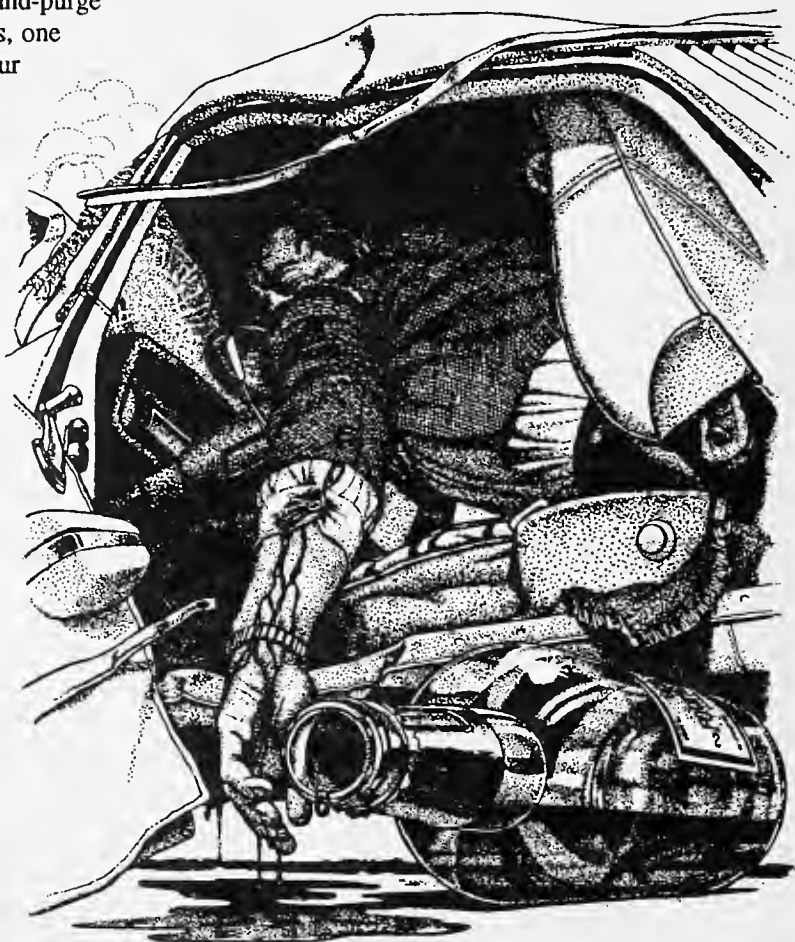
- Drivers under 21 have the highest rates of alcohol-involved fatal crashes.
- The greatest number of fatal motor vehicle accidents for 16-to 19-year-olds occurred at a much lower level of BAC (blood alcohol concentration, or the amount by weight of alcohol in a volume of blood) than for those in older age groups.
- Drivers 16-24 years old represent approximately 17% of all licensed drivers, but are involved in about 36% of all fatal alcohol-related crashes.

Attitudes and Perceptions

- Before turning 18, the average child will see 75,000 drinking scenes on television programs.
- Only half of the fourth graders in a 1987 study knew that beer, wine or liquor is a drug, compared to 87% who knew that marijuana is a drug.
- Nearly a third of high school seniors believe there's no great risk in having four or five drinks almost every day.

Parent Interventions

Myths, peer pressure and exposure to alcohol all create dangerous situations and temptations for young people. Sooner or later your children will face a situation that involves alcohol. What can you do to prepare them to say no? First of all, take time to share with them your own thoughts and beliefs. This kind of discussion opens up a communication channel that can help your children resist peer pressure. Further efforts involve discussing the risk of alcohol use and encouraging attitudes toward alcohol that decrease the chances of a problem.



Risks

Because many adults drink alcohol without encountering problems, some young people may be confused about the risks they face if they drink alcohol. They need to know the following:

- Alcohol is a drug. Although alcohol is an ingredient of beverages that adults can legally buy, it is also a drug. Alcohol can change how a person thinks, feels and acts. Anyone can become addicted to alcohol if they drink enough of it over a long enough period of time.
- Alcohol, like other drugs, has a different effect, depending on the user's age and size and on how much alcohol is used. One-third of American adults don't drink alcohol at all. Most adults who do drink use small amounts of alcohol and don't have alcohol problems.
- A standard serving of beer, wine and liquor each contains the same amount of alcohol, and each has the same amount of risk. Some young people, however, think (1) that there is no difference between a wine cooler or a beer and a soft drink and (2) that there is less alcohol in a wine cooler or beer than in other alcoholic beverages. Here are ways to explain to your children the facts about these misconceptions.

Many young people think beer is no different from soft drinks. They might think this because beer is sold in the same size cans (12-ounce), packaged the same way (six-packs), often sold in the same places (grocery stores) and advertised the same way as soft drinks on television. But beer contains the drug alcohol and soft drinks don't. Over time people who drink enough beer can become addicted to alcohol just as they can if they drink enough wine or liquor.

They may have heard that the percentage of alcohol is lower in beer (around 5 percent) and wine (12 percent) than in liquor (usually 40 to 50 percent). But they may not know that beer, wine and liquor are also usually served in different sizes (12 ounces for beer; 5 ounces for wine; and 1 - 1/2 ounces of 80 proof liquor). So it works out that each one has the same amount of alcohol, it's just more diluted in beer and wine than in liquor.

Instilling Good Attitudes

Many young people know that drinking is a dangerous way to cope with stress, but they may believe that drinking to have fun is not dangerous at all. Those who hold this belief are more likely to have problems with alcohol than those who don't.

The attitude that getting drunk for fun is part of growing up needs to be addressed. Help your children see that getting drunk always increases the risk of harm to health or safety. Even if your child has one drink, it's never too late to say no

to the next one. The attitude they need to develop is that part of growing up is being able to say no to alcohol.

Alcoholism

In teaching young people about alcohol it is important to discuss alcoholism. Medically defined, alcoholism is a disease in which there is impaired control over drinking, preoccupation with alcohol, continued use of alcohol in the face of adverse consequences and distorted thinking. Generally speaking, alcoholism is repeated drinking that causes trouble in the drinker's personal, professional, family or school life. It affects the person physically, psychologically and behaviorally. Alcoholism is not a character weakness or a moral shortcoming; it is an unrelenting, progressive disease which if not treated leads to death or brain damage.

Physical Effects of Alcoholism

To the human body, alcohol is a poison; it kills cells. That's why heavy drinking over a long period of time can eventually destroy the vital organs including the brain, heart, liver and pancreas. Chronic alcoholism also damages the digestive tract and interferes with the immune system, leaving the body vulnerable to many serious diseases.

Psychological Effects

Alcoholics have a constant need to rationalize their drinking in order to explain away the problems it creates. That requires manipulating reality and leads to a type of distorted thinking known as "alcohol-think." One of the most common forms of alcohol-think is "denial"—denying that drinking is a problem, or that any problems are caused by drinking.

Behavioral Effects

Drinking dominates the behavior of alcoholics. They develop a personal relationship with it that they keep private and guard jealously. They give it their time, their money and their attention, usually at the expense of family and friends. They lie for it, deceive for it and think about it constantly. They even risk losing their families and their lives for it. Despite all the harm it causes, they are unable to control it.

Health Risks

Alcoholics have a greatly increased risk of heart disease, cancer, mental illness and many other serious diseases. Furthermore, they don't recover the way other people do. Unless drinking is stopped, the eventual outcome is death—death from organ failure, death from accidents or suicide, death from cancer or common infectious diseases.

Informational Sources and Treatment Programs

There are many resources for parents interested in learning more about alcohol and ways to communicate about it with their children. Here in North Carolina local Mental Health Centers have alcohol and substance abuse programs with professional staff who can provide information and counseling. There are national organizations such as Alcoholics Anonymous that can provide materials and instruction concerning alcohol and alcoholism. A major source for people interested in learning more about alcohol and its effects is the North Carolina Alcohol/Other Drugs Resource Center located in Durham. The Center is operated by the Durham Council on Alcoholism and Drug Dependency, a non-profit corporation. Its services are available to all citizens and organizations in North Carolina. They can be contacted by writing to 3109-A University Drive, Durham, NC 27707 or by calling (919) 493-2881. □

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Health Effects of Indoor Air Pollution

William J. Meggs, M.D., Ph.D.

Prior to the 1980s, the words "air pollution" evoked images of belching smokestacks and dark bands of photochemical smog hanging over cities. One thought of going indoors to get a breath of fresh air. In response to this visible pollution, legislation was passed to limit emissions from smokestacks and to require catalytic converters on automobiles. Then, during the 1980s, a series of studies radically changed our thinking about air pollution. We now recognize that indoor air is polluted with a variety of substances. At the present time we do not have sufficient data to allow solid conclusions about all the health effects of these pollutants, but we have gained an understanding of the problem. Currently, there are no legal standards for indoor air contaminants in homes, schools, and offices, though standards do exist for industry. There are recommendations from professional associations, but these do not have the force of law. In this article I will discuss the known and possible health risks from indoor air pollution and directions for further research.

Exposure

Types of indoor air contaminants are given in Table 1. Many biological substances contaminate the indoor air, but we will only review them briefly here. Cats and

dogs kept as household pets shed danders, and salivary proteins from cats have been identified as a significant indoor aeroallergen. The dust mites *Dermatophagoides farinae* and *D. pteronyssinus* are ubiquitous in the indoor air of homes and cause asthma and rhinitis. Mold spores can cause respiratory allergy. Contamination of ventilation systems with organisms, including thermophilic *Actinomyces* and *Legionella*, has led to outbreaks of respiratory illness. Finally, a number of infectious microorganisms are transmitted through inhalation of infected droplets in the air.

The products of combustion are a major contributor to indoor air pollution. Burning tobacco, gas cook stoves, furnaces, woodburning stoves, and fireplaces produce a variety of particulate, gaseous, and chemical pollutants. In the late 1970s, because of concern about possible health effects of buildings sealed tight to decrease energy losses, the Department of Energy funded studies of indoor air contamination in homes. Homes using gas cook stoves, even in the absence of tight sealing, had higher levels of carbon monoxide, nitrogen oxides, and sulfur dioxide than those permitted in factories.¹ Use

Table 1
Categories of indoor air contaminants

Biologicals	animal dander, dust mites, mold spores, thermophilic <i>Actinomyces</i> , viruses, and mycobacteria
Combustion	carbon monoxide, oxides of nitrogen, sulfur dioxide, hydrocarbons, volatile organic chemicals, and particulates
Radon	a gaseous radioactive element
Volatile Chemicals	formaldehyde, benzene, xylenes, pesticides, and many other organic chemicals

of wood for home heating causes significant contamination of the outdoor air; children who live in homes heated with wood have an increased incidence of respiratory infections.

Radon, a radioactive element, is a gas at normal temperatures and pressures. It seeps from the earth after being formed beneath the earth's surface, and is known to cause lung cancer in humans. The radon problem is discussed on pages 361-365 of this issue.

Air contaminants have been with us for a long time, but only recently have we realized the significance of the problems they pose. With the dawn of the great age of petrochemicals following World War II, production of synthetic chemicals increased, from less than 10 million tons a year in 1945 to more than 100 million tons per year in 1980. We have learned how to fashion synthetic chemicals into fabrics, building materials, clothing,

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cleaning products, fragrances, pesticides, and other products. These materials enter homes, schools, and offices where out-gassing (the process by which volatile components of these products seep into the air), fills the air with low levels of volatile organic compounds.

During the 1980s, the U.S. Environmental Protection Agency (EPA) used Toxic Exposure Assessment Methodology (TEAM) studies to measure exposure of Americans to volatile organic chemicals (VOCs). More than 800 VOCs were identified as contaminants of indoor air, with concentrations significantly higher than those found in the outdoor air.² Concentrations of 20 common VOCs (including benzene, trichloroethane, m,p-xylene, ethylbenzene, and tetrachloroethylene) were measured in the indoor air, outdoor air, drinking water, and in the breath of study subjects. Breath levels correlated with indoor air levels except for chloroform, which was associated with drinking water levels. These data indicate that the main source of exposures to these chemicals is indoor air.

Exposures to pesticides were also studied by the TEAM group. Again, it was found that pesticide levels are much higher in indoor than in outdoor air.³ Most of the exposure comes from personal use of these pesticides, but even the now-banned termiticide chlordane, because it is so persistent, was found in high concentrations indoors.

Health Effects

Asthma and Rhinitis. Asthma and rhinitis are very common ailments in our society. The incidence⁴ of and mortality from⁵ asthma increased during the 1980s. Though comparable data are not available for rhinitis and sinusitis, there is no reason not to think that they have not increased in parallel. For example, a government survey found that chronic sinusitis is the most prevalent chronic illness in the American population. It is tempting to ask whether this increase is related to indoor air pollution, and a search for such a link is worthy of study as indicated by

the known deleterious effects of common indoor air contaminants on asthma and rhinitis; by clinical descriptions of induction of asthma and rhinitis in humans after acute exposure to respiratory irritants; and by work on environmental adjuvants in animal models.

A survey of patients with asthma found that most report exacerbation of symptoms following exposure to indoor air contaminants such as perfumes, cigarette smoke, and pesticides.⁶ Similar results from a survey of patients presenting to the Allergy Clinic at East Carolina University with allergic or non-allergic asthma and rhinitis are given in Table 2. Challenge studies with both perfume⁶ and environmental tobacco smoke⁷ have verified that these substances can induce bronchospasm in asthmatics.

Reactive Airways Dysfunction Syndrome (RADS). RADS is a persistent asthma-like bronchial hyperactivity following a single inhalation exposure to a respiratory irritant.⁸ The acute exposure somehow induces bronchial hyperactivity and an asthma syndrome that is persistent, lasting for months to years, and is difficult to treat. It most commonly occurs in the industrial setting, following an accidental spill or other high-level exposure to smokes, dusts, or irritating organic chemicals. A form of RADS limited to the upper airway (reactive upper-airways dysfunction syndrome, or RUDS)

has recently been described.⁹ Patients with both RADS and RUDS have an intolerance to indoor air contaminants.

Environmental Adjuvants. Proteins contaminating indoor air can induce an immune response, but other environmental chemicals, called environmental adjuvants, can enhance the immunogenicity of those proteins. A number of inhalants (Table 3, next page) have been demonstrated to induce respiratory allergy when co-administered with aeroallergens to animals models. For example, guinea pigs exposed to sulfur dioxide and ovalbumin develop asthma when subsequently challenged with inhaled ovalbumin alone.¹⁰

Autoimmunity and Chemical Inhalants. Traditionally, physicians begin their evaluation of a patient with the new onset of an autoimmune disease with the question, "What medications are you taking?" Pharmaceuticals can induce a number of autoimmune diseases, perhaps the best known of which is Lupus erythematosus. If the patient is on no medications, the illness has traditionally been labeled idiopathic, but is it now accepted that environmental chemicals can induce a number of autoimmune diseases.¹¹ For example, the inhalation of hydrazine, a volatile laboratory chemical similar to the anti-hypertensive drug hydralazine (which is known to induce lu-

Table 2
Reported incidence of sensitivity to common inhalation exposures among 100 patients with asthma and rhinitis

	Allergic Rhinitis (55 patients)	Non-allergic Rhinitis (7 patients)	Allergic Asthma (40 patients)	Non-allergic Asthma (3 patients)
Cigarette smoke	78%	43%	85%	33%
Perfumes	64%	57%	75%	67%
Paint fumes	53%	43%	50%	33%
New fabric	33%	43%	40%	0%
Pesticides	27%	14%	42%	33%
Auto exhaust	27%	14%	48%	33%
Diesel exhaust	25%	14%	42%	33%
Printing ink	24%	29%	17%	0%

Table 3
Examples of environmental adjuvants in animal models

Species	Environmental Adjuvant	Allergen	Reference
guinea pig	sulfur dioxide, ozone, and nitrogen dioxide	ovalbumin	Matsumura et al., 1970 ³¹
guinea pig	sulfur dioxide	ovalbumin	Riedel et al., 1988 ¹⁰
monkey	ozone	platinum	Biagini et al., 1986 ³³
mouse	diesel exhaust particles	Japanese Cedar pollen	Muranaka et al., 1986 ³²

pus), can induce a lupus-like syndrome.¹² The extent to which VOCs in the indoor air contribute to autoimmune diseases is unknown, but given the inadequacy of current treatment for autoimmune diseases and the recovery that is seen in drug-induced autoimmunity when the incriminated medication is discontinued, further investigation of this possibility is warranted.

Cancer. The association between radon and lung cancer is reported in the article that begins on page 361 of this issue, but other environmental contaminants are known to contribute to the risk of cancer. Environmental tobacco smoke increases lung cancer risk in the non-smoking spouses of smokers.¹³⁻¹⁵ Inhalation of organic solvents such as benzene has been implicated in mutagenesis and carcinogenesis.¹⁶

Heavy Metal Toxicity. Mercury is an unlabeled additive sometimes used as a fungicide in paint marketed for indoor use, and cases of acrodynia, or "pink disease," in individuals whose houses were freshly painted has called attention to mercury exposure through contaminated indoor air.^{17,18} Findings in acrodynia include redness and peeling of the hands, feet, and nose, and leg cramps, low-grade fevers, irritability and personality change, proximal muscle weakness, and nerve dysfunction. Using a vacuum cleaner to clean up a liquid mercury spill has lead to mercury poisoning because the vacuum cleaner bag acted as a reservoir, releasing mercury vapor into the air.¹⁹

Respiratory Infections. A number of studies have discussed the relationship between exposure to combustion products and respiratory infections in children. The association is strongest for exposure to environmental tobacco smoke²⁰ and to wood smoke from home heating, though in very small children there is also an association with the use of gas cook stoves.²¹

Sick Building Syndrome (SBS). A number of episodes of illness have been associated with the use of new, energy-efficient buildings.²² SBS is described as eye and respiratory irritation, headache, and difficulty in concentration among occupants of poorly ventilated buildings. The term "sick building syndrome" was proposed by a World Health Organization committee²³ that noted these widespread and well-defined symptoms. Investigators initially fell into two camps, those who thought that SBS represented outbreaks of mass hysteria, and those who felt there was some environmental explanation. A number of studies have incriminated VOCs in the indoor air. A Swedish study documented symptoms in subjects challenged with a mixture of 16 VOCs. The EPA's Human Experimental Research Laboratory at Chapel Hill has found symptoms of respiratory irritation, but not cognitive dysfunction, in normal volunteers exposed to the same VOC mixture²⁴ and also found that after such exposure normal subjects develop neutrophils in nasal washings.²⁵

Multiple Chemical Sensitivity Syndrome (MCS). MCS is another syndrome

that has been associated within indoor air contaminants. It is described as an intolerance to ubiquitous chemical inhalants in which victims have both psychiatric symptoms (ranging from depression and hallucinations to mania) and physical symptoms (ranging from arthritis, bronchospasm, and rhinitis to seizures) triggered by exposure to these inhalants.²⁶ The case definition of MCS requires an initiating exposure similar to that seen in RADS and RUDS,²⁷ and an operational definition has been formulated that states: "The patient with multiple chemical sensitivities can be discovered by removal from the suspected offending agents and by re-challenge, after an appropriate interval, under strictly controlled environmental conditions. Causality is inferred by the clearing of symptoms with removal from the offending environment and recurrence of symptoms with specific challenges."²⁸

MCS has been an area of great controversy, with researchers again falling into the psychological and biological camps. The psychological camp proposes that this syndrome is a somatization disorder and has presented data based on diagnostic interviews and questionnaires to demonstrate increased anxiety and depression in patients relative to controls.²⁹ Conclusions derived using these methodologies have been criticized because patients with medical illnesses can have increased depression and anxiety relative to normal controls,²⁹ and, indeed, a subsequent study found a much lower incidence of psychiatric diagnoses.³⁰ A series of 10 patients satisfying Cullen's case definition for MCS found that all 10

had severe rhinitis, which was sometimes asymptomatic and proposed that MCS may be a form of RUDS with extra-airway manifestations.⁹

Clinical Evaluation of An Environmental Complaint

Often clinicians are faced with patients who claim that their illness was induced by or is exacerbated by exposure to one or more environmental chemicals in the home or workplace. Physicians sometimes dismiss such complaints out-of-hand, but it is important to have and use a systematic approach to environmental complaints. History-taking should include details of exposure and the alleged relationship to illness. Are other individuals in the home or workplace similarly affected? It is very important to obtain information about incriminated chemicals. Businesses are now required to have material safety data sheets (MSDS) on file for every product used and to make these available to workers on request. Patients should be asked to obtain the MSDS for all chemicals to which they are exposed, and not just the one(s) the patient believes are causing the problem. For chemicals used in the home, patients should supply labels that detail the chemical contents of products. The patient should be asked to obtain information on pesticides used in the home by exterminators.

Once exposure data are obtained, information should be sought to determine whether there is a known relationship between the patient's complaint and the exposure. Searches of computer data bases such as Med-line and Tox-line and calls to poison control centers can be helpful in some cases. Texts on toxicology, occupational, and environmental medicine, or specialty texts on the organ system affected can be consulted. MSDS contain information on health effects. Often these measures are sufficient. For example, if a patient blames exposure to organic solvents at work for his respiratory problems, and the MSDS lists respi-

ratory irritation as a health consequence of the products in use, and if other medical diagnosis are ruled out, and if the symptoms are consistent with chemical irritancy, a diagnosis can be given. At this point, there would be sufficient information to involve the employer. The request for an industrial hygienist's evaluation of the workplace may establish that ventilation is inadequate for the product used. The company's occupational physician should be informed of a possible occupational problem. The worker can request an evaluation from the Occupational Safety and Health Administration, or may want to consult his or her labor union if one exists at his workplace.

For alleged exposures occurring in the home, a simple test may be used. See if the symptoms clear when the patient

“The health effects of indoor air pollution is an evolving story, and definitive data are not yet available.”

leaves the home for a few days, and then see if an exacerbation occurs on returning home. One problem with this approach is that many of the incriminated chemicals are ubiquitous in our society. For example, if the patient's symptoms are caused by chlordane, and he or she retreats to another of the 60 million houses that have been treated with this chemical, the test may give a false negative reading.

In many cases it may be necessary to refer the patient to a specialist. Many universities have departments of Occupational and Environmental Medicine, and some but not all allergists and pulmonologists have an interest in respiratory problems stemming from chemical exposures. Referral to a specialist according to the organ system involved may be appropriate in some cases.

Conclusions

The human environment has changed over the past few decades. The health effects of indoor air pollution is an evolving story, and definitive data are not yet available. The extent to which indoor air contaminants contribute to respiratory problems, autoimmune diseases, and other illnesses is not known, but enough information is now available to raise concern. Research into these areas is needed so that measures can be taken to protect our population from the health consequences of indoor air pollution. □

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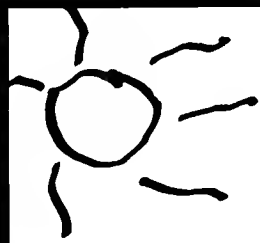
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Radon in North Carolina

Does Exposure Create a Significant Health Risk?

James E. Watson, Jr., Ph.D.

The Surgeon General has warned that radon is the second leading cause of lung cancer deaths in the United States. The EPA attributes 5,000 to 20,000 lung cancer deaths a year in the U.S. to radon.¹ Some radon is present in practically all homes. A person's risk of developing lung cancer depends on the concentration of radon and the length of time the person is exposed.

Sources of Radiation Exposure

Natural sources contribute the largest component of radiation exposure to the population of North Carolina and the nation. Table 1 shows the average annual effective radiation dose equivalents received from various sources by individuals in the U.S., as reported by the National Council on Radiation Protection and Measurements.² Of the natural sources, radon is the most significant, accounting for approximately 55% of the total radiation dose to the population.

Radon is a naturally occurring radioactive gas that has always been present in the environment. The isotope of principal

concern is radon-222, which comes from the radioactive decay of uranium-238 in soil. Uranium-238 gives rise to radium-226, which in turn produces radon-222 which, in turn, undergoes radioactive decay to produce additional radioactive products. The radiological hazard is not radon itself, but the radioactive decay products of radon, called radon daughters or progeny, that deliver the radiation dose to the lungs.

Radon is present as a noble gas in the environment. Because noble gases are inert, radon is inhaled then exhaled, producing very little dose to the lung. In contrast to the gaseous form of radon, radon daughters are particles and when inhaled, they are retained in the lungs. Since these particles are radioactive, retention by the lung results in a radiation dose at the site of deposition. The radiation of concern is alpha particles emitted from polonium-218 and polonium-214. The bronchial epithelium is the critical site of radiation injury.

Table 1
Annual effective dose equivalent in the U.S. population²

Source	Annual effective dose equivalent mrem/yr
Natural Sources	
Radon	200
Other (cosmic, terrestrial, internal)	100
Medical	
Diagnostic x-rays	39
Nuclear medicine	14
Consumer products	5-13
Other (occupational, fallout, nuclear fuel cycle, miscellaneous)	1
Rounded total	360

Until 1984, most of the attention to radon was focused on what are now considered special cases—houses built above the residue from uranium mines in Grand Junction, Colorado, houses built above uranium-containing phosphate deposits in Florida, or houses constructed of materials containing uranium. We now know that elevated levels of radon are more widespread than previously realized. The most common sources of radon are the houses of ordinary U.S. citizens. Most indoor radon comes from natural uranium in the soil and rocks under houses. Radon gas emanates out of the ground (Figure 1)³ and enters the house where it is trapped. Ventilation (air exchange rate)

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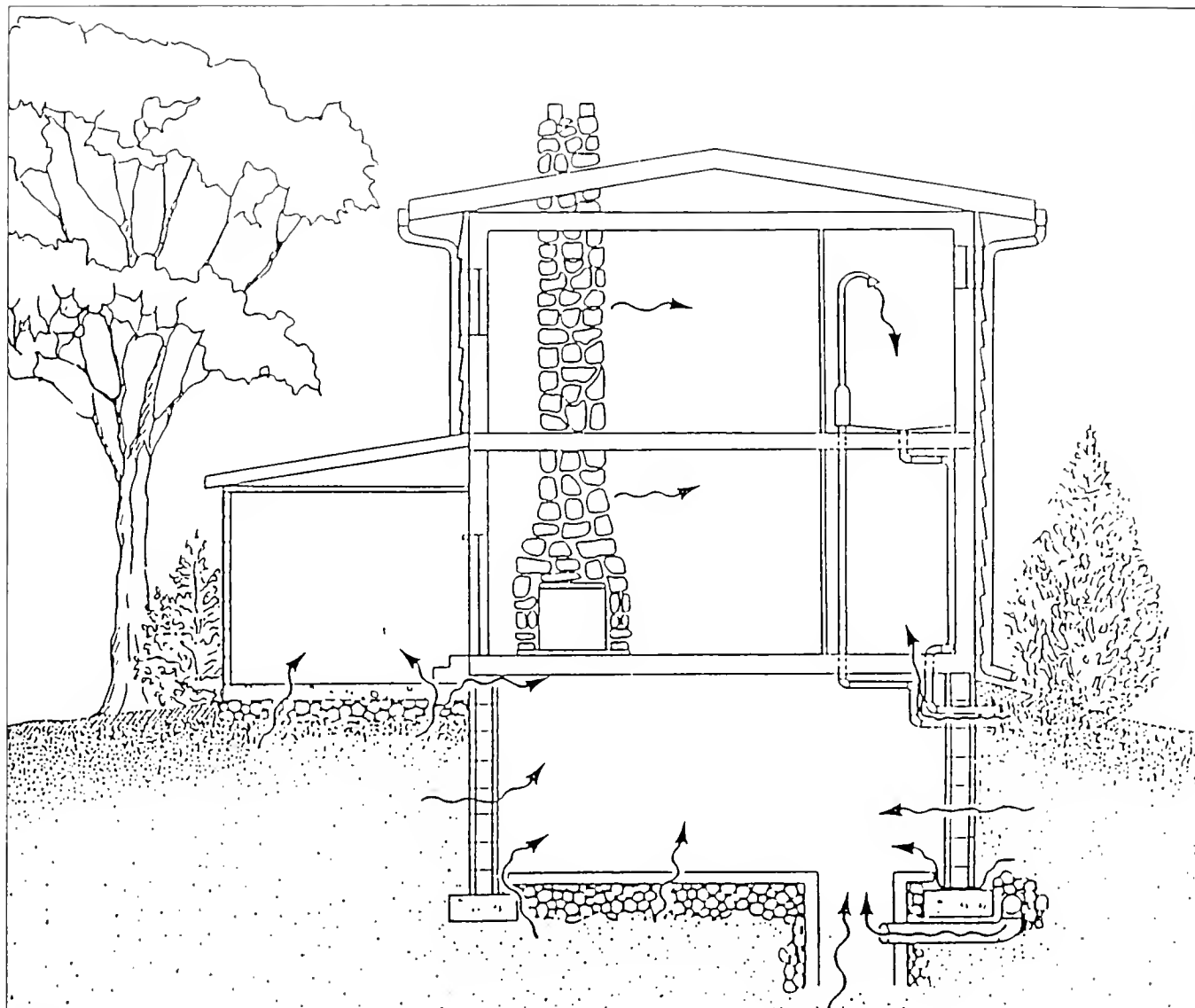


Figure 1: Radon entry routes³

of the house influences the degree to which the concentration builds up.

Another possible source of indoor radon is ground water used in the house. Ground water (e.g., from wells) but not surface water, frequently contains radon, which emanates from water used in showers and sinks. However, unless the concentration of radon in water is very high, water is not a major source of indoor radon and neither is the radon released from construction materials.

Excluding ventilation systems, the concentration of radon in a house depends

largely on three factors: the presence of uranium in the soil under the house, the degree to which radon can move through the soil to the surface, and entry routes from the ground into the house. Obviously, if there is little or no uranium in the soil, there will be little radon in the house. However, even areas that have uranium in the soil may show considerable variation in indoor radon concentrations. Depending on rates of movement and entry of the radon, two adjacent houses can have substantially different concentrations.

Health Effects

Epidemiologic studies of uranium miners show a clear increase in lung cancer among miners exposed to high concentrations of radon. To estimate the risk of lung cancer mortality due to radon exposure in non-miners, it is usually necessary to extrapolate risk data from high-level exposures (miners) to the lower levels found in houses. There is some reluctance to do this since it is not known whether the dose response curve is linear, or whether there are other confounding fac-

tors. Even in the special cases previously referred to in which houses have radon concentrations as high as those that cause an increased incidence of lung cancer in uranium miners, questions have been raised concerning the validity of extrapolating data from mines to houses. Therefore, epidemiologic studies of residents of areas with high indoor radon concentrations are in progress. Although there is no question that radon constitutes the largest source of radiation exposure to the U.S. population, there is controversy on how significant a health risk this is.

The National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR) has estimated lung cancer risk from lifetime exposure to radon assuming a no-threshold model (i.e., one assumes that there is no dose that does not have a risk of effect). Using this assumption, the BEIR committee estimated that lifetime exposure to a radon concentration of 4 picocuries per liter of air (pCi/L) increases the risk of lung cancer mortality by approximately 50%.⁴ (The picocurie is a measure of radioactivity, that is, the number of nuclear disintegrations occurring per unit time). The U.S. Environmental Protection Agency (EPA) uses these data to estimate an excess of 1 to 5 deaths per 100 people exposed for a lifetime (70 years) to 4 pCi/L.¹

As a result of these studies, the EPA has recommended that actions be taken to lower radon concentrations in houses that exceed an average of 4 pCi/L over a one-year period. Taking steps to lower airborne radon concentrations in these situations is called mitigation.

"Radon detectors most often used for indoor radon assessment are charcoal canisters and alpha track detectors."

North Carolina Radon Surveys

Although radon cannot be detected with the senses, it is very easy to measure. The radon detectors most often used for indoor radon assessment are charcoal canisters and alpha track detectors. Charcoal canisters are normally used for short-term measurements, usually a duration of two days to one week. A container of charcoal is opened and placed in the area where the radon is to be measured. Radon is absorbed on the charcoal. At the end of the collection period, the canister is closed and returned to the laboratory for analysis. Usually the charcoal canister should be placed in the lowest liveable area in the house and the house kept closed. These conditions maximize the radon concentration measured.

Charcoal canisters provide "screening measurements" that are fast and relatively inexpensive. If they show less than 4 pCi/L of radon, no further action is normally recommended. However, it must be remembered that recommendations for corrective action are based on annual

average concentration, and screening measurements give results over a short term under conditions expected to maximize radon measurement. If the screening measure-

ment is greater than 4 pCi/L, additional measurements are necessary to evaluate the need for mitigation.

Alpha track detectors are frequently used for longer term (one month to one year) measurements of airborne radon concentrations. This type of detector can be used to obtain an annual average concentration, and is useful when screening measurements indicate a concentration greater than 4 pCi/L. A series of charcoal canister measurements can also be used to estimate the annual average concentration.

Two statewide surveys of radon concentrations in North Carolina houses have been conducted using the charcoal canister method. The first was conducted from December 1986 through March 1987 by the University of North Carolina at Chapel Hill, in collaboration with the N.C. Division of Radiation Protection⁵ to determine whether areas in the state have high indoor levels of radon. In order to obtain geographical dispersion, health department employees living in different areas of each of the state's 100 counties were given five detectors. Instructions specified that each detector should be placed in the lowest liveable area of the house for a four-day period and that the house should be kept closed, except for normal entrance and exit.

A summary of the measured radon concentrations, by region of the state, is shown in Table 2. Concentrations measured in houses in the Coastal Plain were low. Higher concentrations were observed in houses of the Piedmont region, but the highest radon concentrations were found in houses on the western edge of the Piedmont and in the Mountain regions. No area had extremely high indoor radon concentrations, but a significant number of houses in the Piedmont and Mountain regions had concentrations that exceeded 4 pCi/L. Since the houses tested were not randomly selected, the table gives the means for houses tested rather than means for the regions. These values were short-term screening measurements that tend to maximize the measured radon concentration. Annual average results would be expected to be lower.

Table 2
UNC/State survey of radon in North Carolina houses⁵

Region	Houses tested	Mean (pCi/L)	Range (pCi/L)	Houses >4 pCi/L
Coastal Plain	169	0.5	0 - 5	2 (1%)
Piedmont	223	2.1	0 - 28	25 (11%)
Mountains	77	3.3	0 - 31	20 (26%)

Table 3
EPA/State survey of radon in North Carolina houses⁶

Region	Houses Tested	% Houses with basement	Mean pCi/L	Median pCi/L	% Houses >4 pCi/L
Coastal Plain	147	2.7	0.4	0.3	0.6
Basement	4		*	*	*
Nonbasement	137		0.4	0.3	0.0
Eastern Piedmont	158	12.4	0.9	0.6	4.6
Basement	19		2.7	0.9	27.0
Nonbasement	135		0.7	0.5	1.5
Central Piedmont	194	28.3	1.3	0.7	6.3
Basement	52		2.7	1.7	15.5
Nonbasement	133		0.8	0.5	2.3
Western Piedmont	351	26.0	2.0	1.1	8.9
Basement	91		4.0	2.0	20.7
Nonbasement	250		1.3	0.9	4.7
Mountains	440	39.2	3.4	1.7	17.9
Basement	166		6.2	3.1	34.2
Nonbasement	256		1.7	1.2	8.2

* Estimate not given due to small sample size

The State of North Carolina and the EPA collaborated in a statewide survey of radon in 1,290 homes during the late winter and early spring of 1990.⁶ This survey consisted of screening measurements made using charcoal canisters exposed for two days at the lowest liveable area in houses under closed conditions. These houses were randomly selected, which allowed determination of regional and state averages. Since the previous UNC/State survey had indicated that houses in the western part of the state had the highest radon concentrations, sample selection was "weighted" to increase the number of houses surveyed in the Western Piedmont and Mountain regions. The results of this study, categorized by state region and whether or not the house had a basement, are summarized in Table 3.

The mean radon concentrations measured ranged from 0.4 pCi/L in houses in the Coastal Plain to 3.4 pCi/L in the Mountain region, results that were comparable to the earlier survey. The median radon concentrations were lower than the mean values, indicating that more houses had radon concentrations below the mean

values than above. The average radon concentration in basements of houses was three times higher than levels measured in houses without basements. In the Mountains, 34% of the measurements in houses with basements exceeded 4 pCi/L, while only 8% of the measurements in houses without basements exceeded this level. Statewide, the average radon concentration was 1.4 pCi/L, with 6.7% of houses exceeding 4 pCi/L.

A screening survey in Beaufort County (Coastal Plain region) sought to determine whether elevated concentrations of radon were present in homes built above phosphate deposits in that area.⁷ Phosphate rock contains uranium, and elevated indoor radon concentrations have been measured in houses built above phosphate deposits in Florida. In contrast to the observations in Florida, indoor radon concentrations in North Carolina were low. The mean of 77 measurements was 0.4 pCi/L with only three results exceeding 2 pCi/L; the maximum concentration was 3 pCi/L. In Beaufort County no differences were found between indoor radon concentrations in

houses built over phosphate deposits and in those built away from the phosphates. Two factors may contribute to the differences between North Carolina and Florida: The North Carolina phosphate ore has a lower uranium concentration than the Florida ore; and the North Carolina phosphate deposits are deeper below the surface, reducing the amount of radon reaching the ground surface.

Radon Reduction Methods

One obvious method of lowering the radon concentration in a house is to open the windows. Ventilation can provide a substantial reduction in the indoor radon concentration, but its application is usually limited to times when heating and air conditioning are not being used. Ventilation of crawl spaces can help by removing radon before it can enter the living area of the house. If natural ventilation of the crawl space is not sufficient, mechanical ventilation systems can be installed. Ventilating a crawl space requires

measures to protect pipes from freezing.

Mitigation of a house with a basement or one built on a concrete slab is usually more difficult. The first step is to minimize entry of radon by sealing cracks and obvious open spaces such as those around plumbing and wiring entrances in basement floors and walls. The effectiveness of sealing varies because it is difficult or impossible to seal all open spaces, and because the normally negative pressure in a house draws radon in through any remaining spaces. The installation of a sub-slab ventilation system, along with sealing, can reduce indoor radon concentrations to levels below 4 pCi/L. In a sub-slab ventilation system, a pipe is run from the ground beneath the concrete slab through the slab and the house itself so that the other end of the pipe emerges at roof level. This system uses a fan to pull radon from under the slab floor and exhaust it through the roof before it can enter the house. The effectiveness of this system and the number of pipes that must be installed are determined by the ability of radon gas to flow under the slab floor, and this depends on the size and thickness of the aggregate under the slab. Such a system costs \$1,000 or more. A sub-slab system is well suited for use in new construction in areas of known or suspected high radon concentrations.

Radon in Water

The EPA recently proposed a standard of 300 pCi/L for radon in public drinking water supplies. The principal concern about radon in water is not ingestion, but emanation of the radon into the air of the house where it can be inhaled. A rough rule of thumb is that 10,000 pCi/L of radon in water produces an average concentration of approximately 1 pCi/L of radon in the air. The concentration of radon released to the air is, of course, higher in the areas where the water is used, such as a shower. The proposed standard of 300 pCi/L in water should lead to a concentration of radon in air of

0.03 pCi/L. This value is two orders of magnitude lower than the recommended EPA guide for radon in indoor air. The proposed standard for water is stricter than the guide for air because standards for public drinking water are based on a lower allowable lifetime risk.

Based on previous and current work at the University of North Carolina, it is estimated that more than half of the North Carolina public water supplies that use ground water exceed 300 pCi/L.^{8,9} These public water supplies will be required to implement treatment methods to remove radon, probably using aeration of the water. Although the proposed standard for radon in water applies only to public supplies, individuals whose private well water supplies exceed 300 pCi/L are likely to be concerned. Individual water supplies can be treated by aeration or possibly by using granular activated carbon (GAC) absorbers. A GAC system is more economically feasible than aeration but would still cost approximately \$1,000 to install.

Since the principal health risks concern airborne radon, and since in most cases, the most airborne radon comes from soil and rocks, it is reasonable to test the indoor air of a house before its water. If the measured air concentration exceeds the EPA's action guideline of 4 pCi/L, homeowners with private wells should have the water tested. If, after all testing, mitigation is indicated, then the homeowner will need to determine what strategy will be the most cost effective in reducing radon exposure. In most cases, controlling the radon contribution from the soil will be more cost effective than water treatment. □

Author's Note: The names and addresses of companies that provide radon testing and mitigation services can be obtained by contacting the North Carolina Division of Radiation Protection, P.O. Box 27687, Raleigh, NC 27611-7687; or by calling 919-571-4141.

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Postgraduate Medicine

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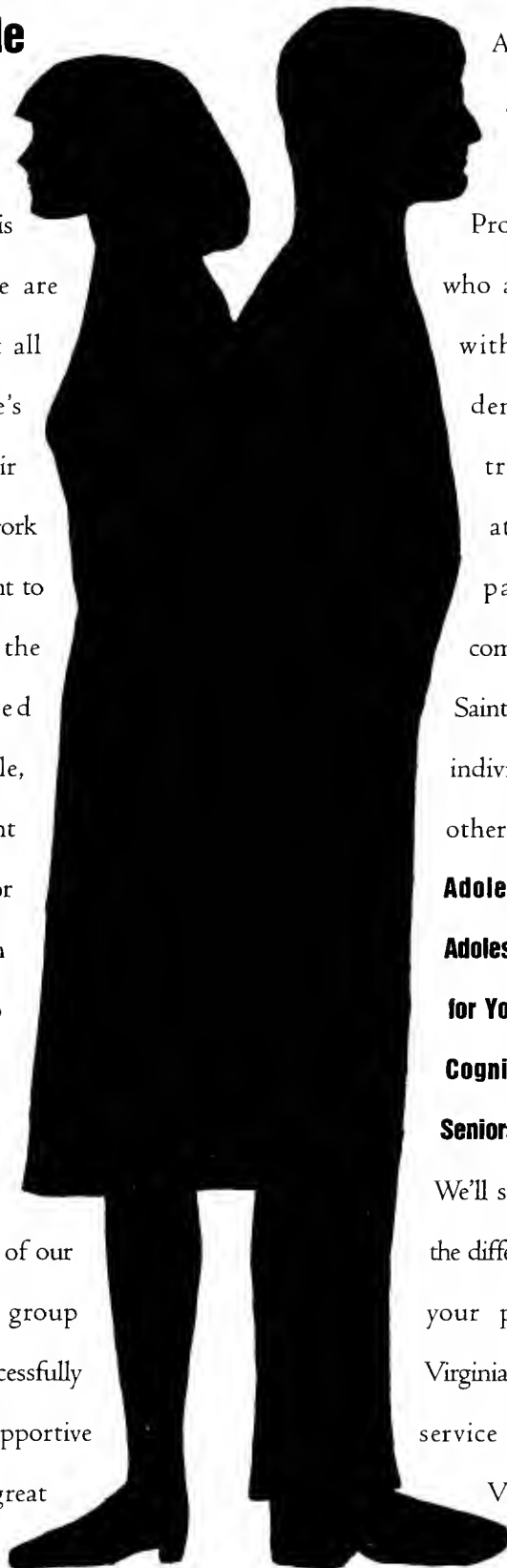
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What Is the Quality of Water in North Carolina?

David H. Moreau, Ph.D.

Is the water in North Carolina safe to drink? Should you swim in it? Are aquatic ecological systems healthy? How do water-related risks compare with other environmental problems? Reliably answering these questions is important not only to the citizens but also to legislators who make laws for managing water quality and to government executives who administer those laws.

Experts often tell us that the quality of water in North Carolina is generally good. While there may be no reason to quarrel with their assessment, the monitoring and reporting on which it is based fall far short of assuring its reliability. This article examines some of the shortcomings of the state's water quality monitoring, reporting, and assessment processes; identifies some initiatives that are being taken to improve the processes; and suggests further steps that would provide more reliable information about water quality.

Reported Conditions

The Division of Environmental Management (DEM) of North Carolina Department of Environment, Health, and Natural Resources (NCDEHNR) provides the most authoritative assessments of water quality currently available. That agency, which manages the water pollution control program, is required under section 305(b) of the federal Clean Water Act (CWA) to produce a biennial report on water quality (the "305(b) report").

The most recent 305(b) report presents a mixed picture of current conditions.¹ The assessment is made according to the system of stream classification used in North Carolina where each segment of every water body in the state is classified according to its highest and best use—water supply, recreation, fishing, etc. In the assessment, each segment is rated as being fully supporting, partially supporting, or not supporting of the use for which it has been classified. Results, summarized in

Figure 1, indicate that 33% of the stream miles that were evaluated are not fully supportive of their designated uses; 35% of the acreage in lakes is not fully supportive; and 24% of the areas of estuaries and sounds are not fully supportive. The report does not break these assessments down by type of use. Stream degradation is most often caused by sediment, and agriculture is identified as the largest single source of this sediment. For lakes, the most frequent form of contamination is from metals, and the largest single source of these is industry. In the estuaries and sounds, the primary cause of degradation is excessive algal blooms, most often caused by agricultural runoff.

Uncertainty About Conditions

The picture painted by this report is incomplete and uncertain, however. One reason is the sheer size and complexity of the task. For instance, there are more than 37,000 miles of named streams, over 300,000 acres of surface covering the 144 most significant lakes, and more than 2 million acres of estuaries and sounds in North Carolina. More than 3,500 permits for point sources of wastewater discharge (required under the CWA) have been issued to municipalities, industries, and owners of wastewater treatment facilities who discharge their effluents in waters of the state. Although nearly 3,000 active community water supplies come under the authority of the federal Safe Drinking Water Act (SDWA), about 58% of state residents get their drinking water from ground water aquifers,² 45% directly from 700-800,000 private wells.

The 305(b) reports provide little information about the quality of drinking water in North Carolina, and there are no other regularly published reports on the quality or the potential threats to drinking water in the state. National drinking water standards have been adopted pursuant to the SDWA, and self-monitoring of the quality of drinking water is required under the conforming statutes and regulations of North Carolina. Finally, after many years of unrealistic, legislatively mandated deadlines, new standards have been added.

Director, Water Resources Research Institute of the University of North Carolina, Raleigh NC 27695.

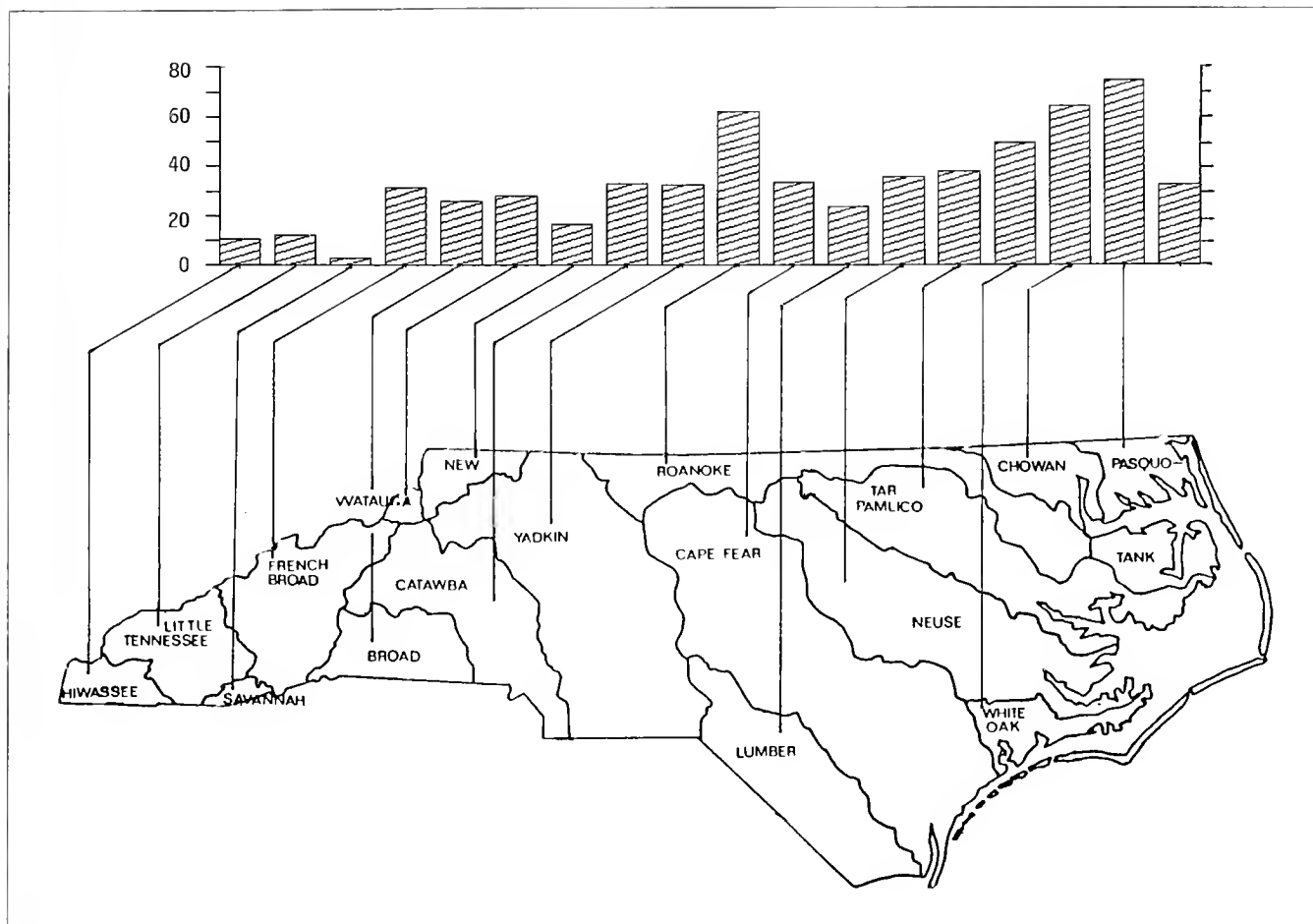


Figure 1: The bar graph above the state map indicates the percentage of stream miles not fully supportive of classified uses.

As of August 1991, maximum levels in drinking water had been proposed or adopted for 19 inorganic chemicals, 19 volatile organic chemicals, and 38 non-volatile chemicals (mostly pesticides). In addition, water purveyors are required to meet maximum contaminant levels for microbiological organisms, turbidity, and radionuclides.³ Public notification of individual violations of these drinking water standards is required, but there is no regular assessment of risks to human health associated with water supplies in North Carolina. Reported violations of water quality standards, even when compiled and reported regularly, are not sufficient. They do not include the threats to health from potential spills that have not yet happened; from potentially harmful substances that are not yet included in the standards; and from activities on the watershed that generate pollutants that have not yet reached the water supply.

Uncertainty arises from the sparse density of ambient water quality stations. The DEM listed 378 such stations as the basis for its report, but that means approximately one station for every 100 miles of stream, and the stations were not located in a manner that would support statistical inferences about

unmonitored stream segments. The DEM did supplement monitoring data with secondary sources of information about land uses and sought the opinions of personnel in regional DEM offices, but information from those sources was not subject to verification. Spatial densities for the sampling of lakes, estuaries, and sounds were not reported. It is clear that additional resources need to be allocated to this task.

Uncertainty also arises from the self-monitoring and self-reporting of the quality of effluents from permitted dischargers. Dischargers must notify the DEM of violations of the limits specified in their permits. The DEM periodically reports violations and any civil penalties to the Environmental Management Commission, but there is no systematic assessment or publication of information about statewide compliance with regulations.

There is no reporting of discharges from nonpoint sources such as from agriculture, forestry, urban stormwater runoff, and other diffuse sources. Different strategies are necessary to manage these sources. The Agricultural Cost Sharing Program provides financial incentives to encourage farmers in the use of best management practices (BMPs) to reduce the runoff of

sediment, nutrients, pesticides, and other contaminants from crop lands. This program is voluntary, however, and there is no monitoring of or reporting on the performance of BMPs after they are put in place.

Nor is there monitoring of runoff from construction sites. The Sedimentation Pollution Control Act, directed primarily at construction activity, requires preparation and implementation of sediment control plans for any land-disturbing activity that covers more than one acre (agriculture is exempted, and forestry is partially exempted). Sites are inspected for compliance with plans, but no monitoring of water quality is required. Violations and civil penalties are reported periodically to the Sedimentation Control Commission, but there is no systematic public reporting of the effectiveness of this program.

One chapter of the 305(b) report is devoted to ground water quality, but the only data given there relate to sources of contaminants at reported contamination sites. There is no assessment of statewide ground water. In fact, no assessment is given of the extent and severity of pollution resulting from contamination incidents. Furthermore, the chapter does not mention the condition of more than 800 inactive hazardous waste sites, nor the conditions around the large number of sanitary landfills.

New Initiatives

U.S. Environmental Protection Agency (EPA) Administrator William Reilly has taken a leadership role at the national level by directing the EPA to develop a set of environmental indicators—a regularly published, well-defined data series comparable to those on the economy. The EPA and other federal agencies are working toward establishing a national Center on Environmental Statistics.

Governor James Martin committed himself in his 1989 inaugural address to appoint a blue-ribbon panel to consider the concept of environmental indicators and make recommendations to him. That panel was appointed in late 1989, and it published its report in December 1990, giving special attention to water quality. The report recommended the following:

- 1) a water quality index by classes of use;
- 2) indicators to identify potential threats to drinking water sources;
- 3) estimates of pesticide sales and use;
- 4) indicators of ground water quality; and
- 5) indicators of quantities of surface and ground water that are withdrawn for various uses.

William Cobey, Secretary of NCDEHNR, has made a

strong commitment to proceeding with development of environmental indicators, despite the present budget crisis in state government. A new section—Environmental Statistics and Geographic Information Systems—has been established in the State Center for Health and Environmental Statistics. That section has been given responsibility for developing and publishing the indicators. An Environmental Indicators Task Force, consisting of representatives from several divisions within the Department, has been charged with developing a strategic plan for implementing the program.

Beyond the present fiscal crisis, however, there will remain an ever-present need to allocate limited resources in an efficient manner. At the national level it has been argued that one tool for better targeting of environmental policy is the concept of environmental risk. By estimating risks to human health, to the ecology, and to human welfare that are associated with different kinds of environmental problems, the EPA's Science Advisory

Board (SAB) has argued that it is possible to compare and rank those problems in common terms.⁴ In the SAB rankings, pollutants in drinking water were one of four that posed relatively high-risks to human health. Habitat alteration and destruction, including the draining and degradation of wetlands, was considered a relatively high-risk problem in the category of natural ecology and human welfare. Toxins, nutrients, biochemical oxygen demand, and turbidity

“Habitat alteration and destruction, including the draining and degradation of wetlands, was considered (by the EPA's Science Advisory Board to be) a relatively high-risk problem in the category of natural ecology and human welfare.”

in surface waters were assigned relatively medium risks with that category. Ground water pollution was ranked among the relatively low-risk problems. North Carolinians may or may not agree with these rankings, but it is clear that we need to establish some priorities in order to address environmental problems in the state. In order to better inform the people of North Carolina and their representatives, we must do a better job of collecting, analyzing, and publishing comprehensible answers to questions discussed in this article.

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Food Safety

Lead, Pesticides, Antibiotics, Hormones, and Irradiation

Linda Frazier, M.D., Dennis J. Darcey, M.D., M.S.P.H., and Ricky L. Langley, M.D., M.P.H.

Every day we seem to hear of some new health threat from food. Individuals can decide how much to eat of foods containing saturated fat or sodium, but they have little or no knowledge of and therefore no control over exposure to environmental contaminants in food or to residues left during food processing. The involuntary nature of these exposures leads to concern about food contaminants that have been shown to cause health problems in humans or in laboratory animals. How great are the risks?

Lead

Lead is a potent neurotoxin, especially when exposure comes during fetal life and early childhood. Lead may leach from certain ceramic glazes or from the solder used to seal tin cans.

Lead poisoning from food may have contributed to the fall of the Roman Empire and to the failure of Scott's expedition to reach the South Pole. Most exposures to lead today, however, are not from food. Instead, people are exposed by certain jobs, by environmental contact with industrial wastes, or by lead-containing dust such as dust or chips from leaded paint.

U.S.-made cans no longer contain leaded seams, and U.S.-made ceramic tableware is generally safe. Some imported foods may be contained in cans with leaded seams, and some pottery may contain leaded glazes. Alcoholic beverages can leach lead from lead-crystal decanters. Lead can be found in drinking water, especially in older homes and some municipal water supply systems where lead solder was used to join pipes. State health departments can often provide consumers with information on water testing services (Table 1).

Table 1: Resources for Further Information

Resource	Telephone No.	Services
U.S. Food and Drug Administration	301-433-3170	See text
U.S. Environmental Protection Agency	202-382-2090	See text
American Institute for Cancer Research Nutrition Hotline	800-843-8114	Provides free publications* and information
National Cancer Institute Cancer Information Hotline	800-4CANCER	Provides free publications* and information
National Pesticide Telecommunications Network Hotline	800-858-PEST	Provides free publications* and information
U.S. Department of Agriculture Meat and Poultry Hotline	800-535-4555	Provides free publications* and information
North Carolina Department of Environment, Health, and Natural Resources	919-733-4984	Answers questions about environmental health risks, can provide information on water testing

From the Division of Occupational and Environmental Medicine, Department of Community and Family Medicine, Duke University Medical Center, Box 2914, Durham 27710.



Pesticides

Pesticides can be quite toxic to humans when substantial doses are absorbed. Acute toxicity can affect many organ systems, depending on the pesticide.¹ Foodborne epidemics, many of which have resulted in deaths,² have occurred when grain was contaminated during transport, when edible seeds have been treated with pesticides, when pesticides have been accidentally added to foods or applied to crops just before harvest time or near a supply of drinking water (in some locations, higher doses may exist in ground water than in food). In general, though, we are not concerned with overt poisoning but rather with determining acceptable limits of exposure to much lower doses of pesticides. To do this a risk assessment is performed.

A risk assessment is a mathematical model that uses data on health consequences of modest to high exposures to estimate potential adverse effects from very low doses (see article on risk assessment on page 377). Often there are few or no direct epidemiologic data from studies in humans, so toxicity studies in animals are used. A person's potential lifetime exposure to the agent from food or drinking water is estimated. A judgment is made about the level of excess risk that is socially acceptable (for example, one excess cancer death per 1 million people).

Cancer is thought to be a potential risk from chronic, low-level exposure to pesticides. Some studies have shown that agricultural workers have a 1.5 to a 2-fold increase in cancers of the lymphatic and hematopoietic systems and the brain.³ Other cancers are not increased. In laboratory rodents, about

50% of all chemicals tested can produce tumors if the dose is high enough.⁴ Some investigators believe that this procedure overestimates the risk of low dose exposures in humans, because the animal studies use such high doses that there is often cell death. Cell death leads to increased mitogenesis, placing the animal at increased risk for genetic mutations.⁴

Pesticide levels in food are monitored by the Food and Drug Administration (FDA) and by other agencies. Between 1979 and 1985, the FDA found that 2.9% of 67,500 domestic food samples and 6.1% of the 33,690 imported food samples contained pesticides above the tolerance level.⁵

It is not generally appreciated that synthetic chemicals are only one source of pesticides in the food supply. Plants produce "natural" pesticides to defend themselves. Ames et al. estimate that humans ingest 5,000 to 10,000 different natural pesticides and their breakdown products.⁶ Of these, 52 have been tested in standard rodent assays and 27 are carcinogenic. Foods containing natural pesticide carcinogens include parsley, celery, mushrooms, potatoes, broccoli, kale, cabbage, collard greens, lettuce, cauliflower, Brussels sprouts, orange juice, mangoes, pineapples, cocoa, jasmine tea, coffee, apples, carrots, cherries, eggplant, endive, grapes, pears, plums, apricots, black pepper, basil, fennel, nutmeg and other spices.⁶

"Foods containing natural pesticide carcinogens include cabbage and pineapples."

Antibiotic Residues

Fifty million dollars worth of meat and milk are discarded annually because of antibiotic contamination.⁷

Small amounts of antibiotics such as chlortetracycline and oxytetracycline are added to poultry and cattle feeds to reduce infections and enhance growth. Dairy cows raised on factory-like farms are particularly prone to stress and disease. They are often given penicillin, streptomycin, neomycin, or polymyxin to treat bovine mastitis. FDA officials reported in 1990 that illegal veterinary drugs were found on 27% of the 1,800 dairy farms checked.⁸ Fortunately, antibiotic residues are seldom found in commercial meats, but the animals can develop antibiotic-resistant microflora in their digestive tract. There are concerns that antibiotic resistance might be transferred to human pathogens and that even trace antibi-



*Consumer-oriented publications available from the organizations in Table 1 include: AICR: "Dietary Guidelines to Lower Cancer Risk," "All About Fat and Cancer Risk." NCI: Diet, Nutrition, and Cancer Prevention: The Good News," "Everything Doesn't Cause Cancer," "Cancer Facts for People Over 50." NPTN: "Citizen's Guide to Pesticides." USDA, The Meat and Poultry Hotline: "A Quick Consumer Guide to Safe Food Handling" and "Preventing Foodborne Illness."

otic residues could present a risk to those individuals who have antibiotic-mediated hypersensitivity reactions.⁷

Tinkering With Elsie's Hormones

American consumers may soon be drinking milk from cows treated with a genetically engineered bovine growth hormone, known as recombinant bovine somatotropin (BST). BST is a natural hormone that stimulates endogenous milk production. The synthetic analog, rBST, when injected into dairy cows, can increase milk production by at least 14%.⁹ Since 1985, the FDA has allowed milk from BST-treated cows to be sold in the U.S., and approximately 20,000 U.S. dairy cows have been treated in an experimental program.¹⁰ The FDA is scheduled to make a final decision about whether to allow the commercial use of BST sometime this year.

Few drugs, however, have generated as much controversy as BST. Opponents of its use have raised health, ethical, social, and economic issues to challenge FDA approval.¹¹ Groups opposed to the use of BST charge that the milk produced may not be safe for the consumer, that the treatment may not be safe for dairy cows, and that any increase in milk production may lead to a milk glut, reducing the price of milk and driving small dairy farmers out of business.

Congress convened an independent National Institutes of Health Advisory Panel in December 1990, to examine the health and safety concerns raised by critics of BST use. The panel concluded¹⁰ that use of BST was safe, since it is normally present in trace amounts in milk from unsupplemented cows and has no biological affect on humans. BST exerts its effects, in part, by stimulating the hepatic synthesis and secretion of a secondary hormonal mediator, insulin-like growth factor (IGF-I). Human digestive enzymes break down BST and IGF-I in the gut.¹² Furthermore, species specificity in the action of BST was

BST does not cause changes in milk composition of any practical importance to consumers and does not affect the growth of lactic starter cultures used to manufacture dairy products, such as yogurt and cheeses.¹⁴

There was concern about the potential change in IGF-I levels in milk used for preparation of commercial infant formulas. However, the concentrations of IGF-I in milk produced by BST-supplemented cows is well within the endogenous levels of bovine and human milk and should have no impact on milk safety.¹³ And, in any case, the high level of heat normally used to process infant formulas inactivates IGF-I.¹⁵

The NIH panel said that the general health of dairy cows was not appreciably affected, but called for more research on the affects of BST on mastitis, a common inflammation of the udder that is the principal reason for giving antibiotics to dairy cows. Opponents of BST claim that it may lead to the use of more antibiotics and therefore higher residual antibiotic levels in milk.

The potential for widespread use of BST has raised basic questions about the economic solvency of the family farm. Opponents claim that BST, by revolutionizing the dairy industry, will force many small farmers out of business.¹¹ In the end it may be economic and political considerations that decide the fate of BST, even if approved by the FDA on human health grounds.

Food Irradiation

Food irradiation helps to solve problems of food spoilage, but it engenders alarm among some consumers. The goals of food irradiation include: reduction of food spoilage and pathogenic organisms; elimination of parasites and control of insect infestation in food products; prevention of sprouting and delaying of ripening of certain fruits and vegetables; reduction in the use of or avoidance of chemical preservatives, pesticides, or fumigants; and reduction in energy expenditure for food preservation.¹⁶ Since thousands of people worldwide die each year from eating food contaminated by bacteria or toxins, proponents believe that food irradiation may help ease food poisoning and starvation.

Food may be irradiated with gamma rays, electrons or x-rays.^{17,18} Radiation itself was defined as a food additive under the 1958 Food Additive Amendment to the Federal Food, Drug, and Cosmetic Act.¹⁹ The irradiation of food was first approved by the FDA in 1963 to kill insects in wheat. Since then, irradiation has been approved to control *Trichinella* in pork, to inhibit the growth and maturation of fresh foods, to disinfect food of arthropod pests, to disinfect dry or dehydrated herbs, seeds, spices, teas, and vegetable seasonings of microbes.²⁰ Doses of radiation that may be used to irradiate foods have been limited by the FDA.

Irradiation, like other food processing techniques, causes chemical changes in food that may alter its nutritional content.

"BST does not cause changes in milk composition of any practical importance to consumers and does not affect the growth of lactic starter cultures used to manufacture dairy products, such as yogurt and cheeses."¹⁴

demonstrated in the late 1950s when it failed to stimulate growth of children with pituitary dwarfism. It appears that the human somatotropin receptor has evolved sufficiently that it neither binds to nor is activated by BST or by somatotropin from any non-primate species.¹³

Certain vitamins including vitamins A, B, C, E, and K are partially destroyed by radiation^{16,17} as they may be by thermal heating. Irradiation changes the flavor of fatty foods,²¹ but the nutrient quality of carbohydrates, proteins, and minerals are little affected by irradiation with doses less than 100 kRad (1kGy). Higher doses may cause significant losses of essential nutrients.¹⁹

Since microorganisms differ in their radioresistance, very high doses of radiation may be needed to sterilize food. The lower doses currently used decrease the total microbial load without inducing complete sterility. Therefore, the usual hygienic precautions are necessary in handling irradiated food, just as with non-irradiated food. These include subsequent refrigeration or preservation at low pH or at low water activity.¹⁶ One advantage of irradiation is that food can be treated inside a protective package, helping to prevent subsequent infection of the packaged food.²¹

Naturally radioactive elements such as carbon-14, potassium-40, and tritium are present in all foods.²¹ Irradiation produces insignificant amounts of radioactivity in food.^{21,22} By 24 hours after irradiation, most of the radioactivity has decayed below natural background levels. Irradiation of food also produces radiolytic products,^{17,21} but these are, in general, identical to chemical products normally present. Numerous animal and human feeding studies have shown no significant adverse health effects from eating irradiated food.

Opponents of food irradiation feel that manufacturers may use the process to "clean up" substandard food.²³ Other criticisms include the government's proposal to use nuclear waste as a radiation source, the loss of vitamins from irradiated food, the failure of irradiation to destroy toxins even though it kills bacteria, and the absence of labels on irradiated food.¹⁸ Proponents of food irradiation respond that machine sources of irradiation produce no nuclear waste;¹⁸ that irradiated food should be part of a well-balanced diet and not a sole source of nutrients;²¹ that, where there is a possibility of toxin production, food should be stored in cool, dry places as with storage of conventional foods;^{16,21} and that the FDA requires irradiated food to carry the international logo for irradiated food and one of two phrases: "Treated With Radiation" or "Treated By Irradiation."

Who Protects the Food Supply?

Several federal agencies have responsibility for safeguarding our food supply. As a part of the U.S. Department of Health and Human Services, the FDA is the primary federal agency responsible for ensuring the "safety and wholesomeness" of foods sold in interstate commerce. The FDA administers the provisions of the Food, Drug, and Cosmetic Act of 1938, which has been modified over the years to include pesticides, chemicals, food and color additives. The FDA also administers other

food-related federal statutes such as the Fair Packaging and Labeling Act (1966) that allows the FDA to determine labeling requirements for all foodstuffs.

The FDA also tests food for pesticide residues and enforces the tolerance levels set by the EPA. It also regulates all veterinary drugs, sets maximum tolerance levels for drug residues in

"(The Delaney clause) has been controversial because of uncertainty about the validity of the animal feeding tests used to establish carcinogenicity."

milk, eggs, raw meats, and poultry, and sets limits on chemical contaminants in fish. Its primary responsibility for regulating food additives derives from the Delaney clause that prohibits approval of food additives that cause cancer in animals or humans, or that have been shown to be carcinogenic by any other appropriate test. This clause has been controversial because of uncertainty about the validity of the animal feeding tests used to establish carcinogenicity.

Food items containing more than 2% poultry or 3% meat are regulated by the U.S. Department of Agriculture (USDA). The USDA assumes the responsibility for the safety of meat, poultry, and eggs sold through interstate commerce. The Food Safety and Inspection Service inspects meat and poultry products and regulates food and color additives in meat and poultry. The Agricultural Marketing Service inspects eggs and egg products and has been instrumental in setting national standards for organic foods.

The EPA approves the use and application of pesticides and sets tolerance levels for pesticide residues in foods. The EPA also establishes national drinking water standards for public drinking water supplies, but the FDA regulates bottled water based on these standards. Other federal agencies involved in food regulation include the National Marine Fishery Service, which offers a voluntary, fee-for-service, fish inspection program. It is estimated that about 10% of the seafood consumed in the U.S. is inspected under this program.⁷

State and local governments have retained primary responsibility for monitoring the contamination of milk and dairy products with bacteria and antibiotics. The states also test eggs for Salmonella. The National Shellfish Sanitation Program, a voluntary program in 29 states and the District of Columbia, monitors shellfish for contamination and has authority to close waters judged unsafe for harvesting. Many states also have programs to monitor pesticide residues in produce and to enforce health and labeling requirements in supermarkets and restaurants.

Conclusions

There are many risks to a safe food supply, some great, some small. Contamination by microorganisms poses the greatest risk. Bacterial food poisoning can cause obvious, significant health problems. Food inspections and proper attention to food handling and cooking can greatly reduce health hazards from contamination by microorganisms. Other contaminants in food pose less severe health risks and data on human health effects are usually not available. In these cases, risks are estimated from mathematical models that contain a great deal of uncertainty.

Antibiotics can induce allergic reactions in sensitive individuals. Chronic exposure to even low levels of pesticides may be carcinogenic. Lead causes neurologic damage, especially in infants. Regulations to keep levels of these agents below certain thresholds make sense. No evidence suggests serious health risks from treatment of food with radiation to enhance shelf life, or from treating food animals with growth hormone.

Should consumers buy only "organically grown" food? Consumers may wish to support agricultural practices that are perceived as less harmful to the environment, but the health benefits from consumption of organically grown foods are less clear. Organically grown foods may have lower levels of some contaminants, but controlled studies would be necessary to document this. Organically grown foods still contain non-synthetic pesticides. The postulated health risks from food contamination pales in comparison to health risks from certain occupational exposures, failure to use automobile seat belts, high-risk sexual activity, alcohol and drug abuse and, especially, tobacco smoking. Caution in choice and selection of what we eat is prudent, but we are fortunate to have a basically safe food supply. Bon Appetit! □

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Environmental Risk Assessment

Estimating Risks Contaminants Pose to Our Health

Gwendolyn S. Powell, M.D., M.P.H.

Risk is a measure of the probability of an adverse event.¹ Risk assessment for environmental pollutants is a method of estimating the probability that adverse human health events will result from exposure to pollutants at defined levels. New chemicals are regularly introduced into modern industrial processes and therefore into our environment. In order to justify and implement new technologies, the risks associated with progress must be assessed and judged acceptable or not. Risk assessment methods have been developed to quantitatively estimate the risk that environmental contaminants pose to the health of exposed populations.

In this discussion, the rationale for performing risk assessment, the requirements for completing a study, and the methods used will be examined.

Rationale for Risk Assessment

A degree of risk is associated with most activities. Risk may be voluntary, such as that associated with recreational activities, or involuntary, such as that from exposure to environmental contaminants. The level of risk that is acceptable is different for individuals and must be decided for groups by society. In general, involuntary risks are not tolerated at levels that would be acceptable for voluntary risks.

Our culture expects to have clean air and water and safe food. To ensure the cleanliness and safety of our environment, we must undertake control of pollution based on the degree of risk posed by various pollutants. Therefore, environmental risk assessment is a prerequisite for environmental policy-making. Estimating the risks associated with exposure to various pollutants provides a scientific basis for regulations designed to protect public health. The information generated may also be used to set priorities, to determine cutoff levels or standards for acceptable exposure, to weigh the benefits of activities with respect to their risks, and to conduct risk management.

Components of Risk Assessment

Risk assessment is performed by:²

1. Evaluating health hazards,
2. Examining dose-response relationship(s)
3. Estimating exposure, and
4. Characterizing the risk.

Depending on the substance evaluated, the process may include one or all four steps.

Health Hazard Assessment

Environmental risk assessment begins with determining the nature of the health hazard. Environmental agents causing adverse health effects include human carcinogens, somatic or germ cell mutagens, or organ and/or tissue toxicants. The risk calculations ultimately performed in the quantitative assessment will depend on the type of hazard and whether a threshold of effect is assumed.

Animal studies, in vitro experiments, structure-activity similarities to compounds of known hazard, and human epidemiologic studies may be used to assess health hazards. Although ideal for hazard evaluation, epidemiological studies are not usually available. When they are available, epidemiologic studies should be evaluated as to: the use of exposure levels comparable to those anticipated in the environment; whether the sample size is large enough to demonstrate an effect; the choice and characteristics of exposure and control groups; an assessment of latency; the length of follow-up (short vs. long-term exposures); the outcome measures used; and the quantification of data. Effect should be measurable as an incident rate, i.e., the number of new cases during a time unit divided by the population at risk. Studies that do not quantify results may be used to support a causal link between exposure and illness but cannot be used to determine dose-response.

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Risk to humans may be extrapolated from positive animal studies. For example, chemicals that are animal carcinogens are often assumed to be human carcinogens. Animal studies should have as many similarities to the human risk group as possible including dose rates and ranges, ages of exposed subjects, choice of control group, and length of study. The species most similar to humans in target effect or most sensitive to the toxicant should be used.³ When animal data are used, the dose rate must be converted from animal to human exposure equivalent units such as milligrams per kilogram per day.

Qualitative information from other sources may be used to support the findings from animal experiments and human epidemiologic data. In vitro experiments may help define the mechanism of the effect. Any structure-activity relationship to similar compounds of known toxicity may add weight to the finding of health hazards. If no causal relationship between exposure and health effects is defined by examining the data described above, the assessment is complete. If adverse effects are expected, the dose-response relationship should be explored.

Dose-Response Assessment

The relationship between the magnitude of exposure to the study chemical and the incidence of adverse health effects (the dose-response) must be determined to quantify risk. Data may be extrapolated from animal studies or derived from human epidemiological evaluations as noted above. Factors to be considered in modeling the dose-response relationship include intensity, duration, route, frequency, and rate of exposure.

Exposure levels of interest include: 1) the no-observed effect level (NOEL); 2) the no-observed adverse effect level (NOAEL); and 3) the lowest-observed adverse effect level (LOAEL). At the NOEL no effect of any type is produced whereas, at the NOAEL, effects such as non-adverse physiological changes are seen. The LOAEL is the dose at which adverse effects are first noted to be significantly increased in exposed compared to control subjects.

Factors that modify the interaction between the substance and the exposed subjects such as chemical properties, metabolic pathways, or predisposing conditions among those exposed are important in determining the dose response. The mechanism of toxicity is important in determining the risk of effect at various doses because agents whose toxicity exhibit a threshold for response (non-zero threshold chemicals) are evaluated differently from those capable of causing risk at any level (zero threshold).

Non-zero threshold chemicals produce no adverse effects below a certain dose or threshold that can be determined experimentally. Organ and tissue toxicants and developmental toxicants are generally considered to have a non-zero threshold. Some threshold of exposure must occur before an adverse effect is noted and below which no effect or no adverse effect occurs.

In assessing the risk of non-zero threshold chemicals, the

methods used must take into consideration the no-observed effect level or no-observed adverse effect level and modify these values by using a calculated safety factor. This method of risk assessment is the safety factor method. Any equation used to fit the experimental data to a mathematical curve should be equally good at predicting response across the range of exposure.

Mutagens and carcinogens can produce an adverse effect at any level and are therefore zero threshold toxicants. The no-observed effect level is assumed to be zero and the no-observed adverse effect level is irrelevant. A method known as risk analysis uses the lowest-observed adverse effect level to assess the risk of zero threshold toxicants. Risk may occur at any level, but it may not be practical to determine it at very low doses; the response curve and therefore the measure of risk must be assumed to be below experimental doses.

Although several models may be used to predict risk at low levels of exposure, the linear model is simple and produces a conservative result. When using the linear model, there is interpolation between the lowest experimental dose that produces a response and zero. This method should not underestimate risk and is logical since the mechanism of toxicity operating at the lowest experimental dose is likely to be the mechanism operating at even lower doses.³

Estimating Exposure

Once a model has been developed to describe the dose-response relationship, exposure must be measured for the population at risk. The risk group consists of those exposed to the study chemical at concentrations above background. It is necessary to determine who will be (or was) exposed and at what dose, the source and route of exposure, and what other relevant exposures may contribute to or modify the effect of the chemical in question. Exposure estimates may be made for actual exposure situations or for expected situations.

When assessing the risk of actual past exposures or current environmental conditions, exposure estimates may use available environmental monitoring data relevant to the exposed group. Actual data are used to calculate a dose based on assumptions about the characteristics of the exposure. In contrast, risk assessments done to predict health hazards anticipated from an environmental agent must use hypothetical exposures based on the likely sources of the pollutants (e.g., emissions, spills, or discharges). Different estimates may be made for varying conditions such as short-term high dose exposures or lifetime low level exposures.

Whether exposures are actual or hypothetical, they must be characterized in detail. The characteristics of the hazardous material(s) are important in determining the exposure since physical state, melting and boiling points, molecular weight, etc. will influence the dose received by the population at risk and also will determine the uptake, reactivity, residence time,

distribution, and breakdown of the material in the environment. Important exposure characteristics include the intensity or level, frequency, route, and duration of exposure. These characteristics are affected by the source (air versus water, etc.), amount, area of distribution, ecological distribution, and types of containment (for storage, use, or disposal) of the chemical under study.

The size and character of the exposed population (population at risk) must also be determined. Factors such as travel and patterns of indoor and outdoor activity may be relevant to the assessment of risk since they may modify the dose of chemical received.

All sources of exposure should be considered, and upper estimates should be used to ensure a conservative assessment. When actual measurements are not available for current exposures or when anticipated exposures are studied, models specific to air, ground water, or surface water contaminant concentrations may be used to calculate exposure.

Characterizing the Risk

Using defined exposure variables and a predicted dose-response relationship, the expected number of adverse health effects can be calculated. The calculations are straightforward and need no extrapolation when the dose received by the risk group is within the range for which we have experimental data. Since this is rarely the case, we may use the safety factor method, in which the experimentally derived no-observed effect level or no-observed adverse effect level from the most sensitive animal species or human study is adjusted by a safety factor.

The degree of uncertainty in numerical measurements of health risk, dose response, and exposure are quantified and used to derive the safety factor. The estimate of the risk of adverse health events is then further adjusted for control group responses. Calculations may be made to estimate individual excess risk or to predict the number of excess cases of illness in the population as a result of exposure.

The quantitative result of a risk assessment must be qualified by descriptive terms to arrive at an overall picture of predicted risk. Decision points occur at each step of the assessment where effects must be inferred, and these decisions should be discussed. A comprehensive risk assessment includes a discussion of the assumptions made, of the levels of uncertainty in calculations, and of the risk assessment policies employed. Sources of error that may arise from the quality or quantity of data should be discussed as should study design factors such as choices of experimental and control groups, route and duration of exposures, and any confounding variables. The number of studies available for analysis and their duration as well as the sizes of exposed and control populations and any assumptions made when extrapolating the dose-response curve are important.

Once all relevant calculations have been made and the

assumptions and sources of error are discussed, the completed risk assessment may be used in environmental decision-making.

Discussion

Determining the health risks of low-level environmental contamination is a difficult process that involves subjective as well as objective methods. In addition to the difficulties posed by quantitative risk assessment, especially where few scientific data are available, many other environmental factors including lifestyle, physical factors, and other chemical exposures that may cause or contribute to an illness will influence the health risks associated with a particular chemical. Data from risk assessments may be applied in environmental policy-making, be used to predict the results of preventive approaches to pollution, or be used as background information to assess the medical concerns of patients exposed to environmental pollutants. Since risk assessment is not an exact science, care must be taken in using the results for risk management.

Health risk assessment is used to establish priorities in environmental policy-making, to set standards and levels, and to develop regulations to protect public health. In the 1970s, the Carcinogen Assessment Group of the U.S. Environmental Protection Agency (EPA) evaluated suspected carcinogens for health risk and established risk assessment guidelines for specific issues including exposure assessment, carcinogens, developmental toxins, mutagens, and chemical mixtures, thereby establishing the prominence of risk assessment in the area of environmental health.²

Acceptable risk must be defined to provide a framework for risk management decisions. Acceptable (permissible) lifetime risk for exposure to carcinogens of one in one million has been used by the EPA compared to one in one thousand for a working lifetime used by the Occupational Safety and Health Administration. Risk management decisions, although based on risk assessments, must be made within an arena of social, political, economic, and statutory constraints and considerations. The EPA uses risk assessment to manage risk by setting internal priorities, selecting agents that should be regulated, deciding about source control and providing information to policy-makers regarding the implications of control options.³

Risk assessment can be used to predict the impact of pollution control methods. Models of currently operating industrial processes that emit contaminants can compare the results to be expected by installing control methods for the process. The comparison will illustrate the costs and benefits of the proposed control technology and provide a basis for decision-making. Likewise, the impact of regulatory risk management decisions may be defined through hypothetical modeling of before-and-after scenarios.

Quantitative environmental risk assessments cannot predict the likelihood that any given individual will develop an

environmentally related illness.⁴ The multifactorial nature of many illnesses and the extreme variability in individual susceptibility limit the feasibility of predicting illness in an individual. Factors that influence individual susceptibility include rate of chemical absorption, method of transportation to and within cells, target organ effect, chemical resistance, and genetic material repair potential. There is variability in distribution, metabolism, retention, and excretion of environmental chemicals. Differences in these factors result in part from biological variables such as age, race, gender, and genetic constitution.

Many biological markers of chemical exposure are available. For example, individuals may be tested for chromosomal aberrations, activity of mixed function oxidases, amount of hemoglobin adducts, and alterations in immunological markers. Also assays may be done to detect the chemical itself, or its metabolites, in body fluids. Biological markers may be affected by exposures other than to the chemical in question and are not interpretable on an individual basis. They may be useful for assessing the degree of exposure of a population, but are not sufficient to predict resulting health effects.

Risk assessment cannot establish whether an individual's illness was caused by exposure to an environmental contaminant. Although the information may form an important foundation for investigating individual cases, each illness must be thoroughly worked up medically. Characteristics of the chemical exposure and of the exposed individual are important in

evaluating a potential environmental illness. The type of exposure must be well-defined through the occupational and environmental history and any supportive objective data. Assimilation of all relevant data is required to reach a "best guess" about the relationship between exposure and disease.

Environmental risk assessment is a developing science with expanding applications in the area of risk management. When used with a full understanding of its utility and limitations, risk assessment adds a vital scientific basis to decision-making in environmental health. □

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Edited by Daniel Sexton, M.D.

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—*Mary Little*

Watch out when you are getting all you want.
Fattening hogs ain't in luck.

—*Joel Chandler Harris*

The best way to get on in the world is to make people believe
it's to their advantage to help you.

—*Jean LaBruquere*

Success covers a multitude of blunders.

—*George Bernard Shaw*

It takes 20 years to become an overnight success.

—*Eddie Cantor*

If at first you don't succeed you're running about average.

—*Anonymous*

Success is counted sweetest by those who ne'er succeed.

—*Emily Dickenson*

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Warnings: Verapamil should be avoided in patients with severe LV dysfunction (eg, ejection fraction < 30%) or moderate to severe symptoms of cardiac failure and in patients with any degree of ventricular dysfunction if they are receiving a beta-blocker. Control milder heart failure with optimum digitalization and/or diuretics before Calan SR is used. Verapamil may occasionally produce hypotension. Elevations of liver enzymes have been reported. Several cases have been demonstrated to be produced by verapamil. Periodic monitoring of liver function in patients on verapamil is prudent. Some patients with paroxysmal and/or chronic atrial flutter/fibrillation and an accessory AV pathway (eg, WPW or LGL syndromes) have developed an increased antegrade conduction across the accessory pathway bypassing the AV node, producing a very rapid ventricular response or ventricular fibrillation after receiving I.V. verapamil (or digitalis). Because of this risk, oral verapamil is contraindicated in such patients. AV block may occur (2nd- and 3rd-degree, 0.8%). Development of marked 1st-degree block or progression to 2nd- or 3rd-degree block requires reduction in dosage or, rarely, discontinuation and institution of appropriate therapy. Sinus bradycardia, 2nd-degree AV block, sinus arrest, pulmonary edema and/or severe hypotension were seen in some critically ill patients with hypertrophic cardiomyopathy who were treated with verapamil.

Precautions: Verapamil should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of overdosage. Verapamil may decrease neuromuscular transmission in patients with Duchenne's muscular dystrophy and may prolong recovery from the neuromuscular blocking agent vecuronium. It may be necessary to decrease verapamil dosage in patients with attenuated neuromuscular transmission. Combined therapy with beta-adrenergic blockers and verapamil may result in additive negative effects on heart rate, atrioventricular conduction and/or cardiac contractility; there have been reports of excessive bradycardia and AV block, including complete heart block. The risks of such combined therapy may outweigh the benefits. The combination should be used only with caution and close monitoring. Decreased metoprolol and propranolol clearance may occur when either drug is administered concomitantly with verapamil. A variable effect has been seen with combined use of atenolol. Chronic verapamil treatment can increase serum digoxin levels by 50% to 75% during the first week of therapy, which can result in digitalis toxicity. In patients with hepatic cirrhosis, verapamil may reduce total body clearance and extrarenal clearance of digitoxin. The digitoxin dose should be reduced when verapamil is given, and the patient carefully

monitored. Verapamil will usually have an additive effect in patients receiving blood-pressure-lowering agents. Disopyramide should not be given within 48 hours before or 24 hours after verapamil administration. Concomitant use of flecainide and verapamil may have additive effects on myocardial contractility, AV conduction, and repolarization. Combined verapamil and quinidine therapy in patients with hypertrophic cardiomyopathy should be avoided, since significant hypotension may result. Concomitant use of lithium and verapamil may result in a lowering of serum lithium levels or increased sensitivity to lithium. Patients receiving both drugs must be monitored carefully. Verapamil may increase carbamazepine concentrations during combined use. Rifampin may reduce verapamil bioavailability. Phenobarbital may increase verapamil clearance. Verapamil may increase serum levels of cyclosporin. Verapamil may inhibit the clearance and increase the plasma levels of theophylline. Concomitant use of inhalation anesthetics and calcium antagonists needs careful titration to avoid excessive cardiovascular depression. Verapamil may potentiate the activity of neuromuscular blocking agents (curare-like and depolarizing); dosage reduction may be required. There was no evidence of a carcinogenic potential of verapamil administered to rats for 2 years. A study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor, and delivery only if clearly needed. Verapamil is excreted in breast milk; therefore, nursing should be discontinued during verapamil use.

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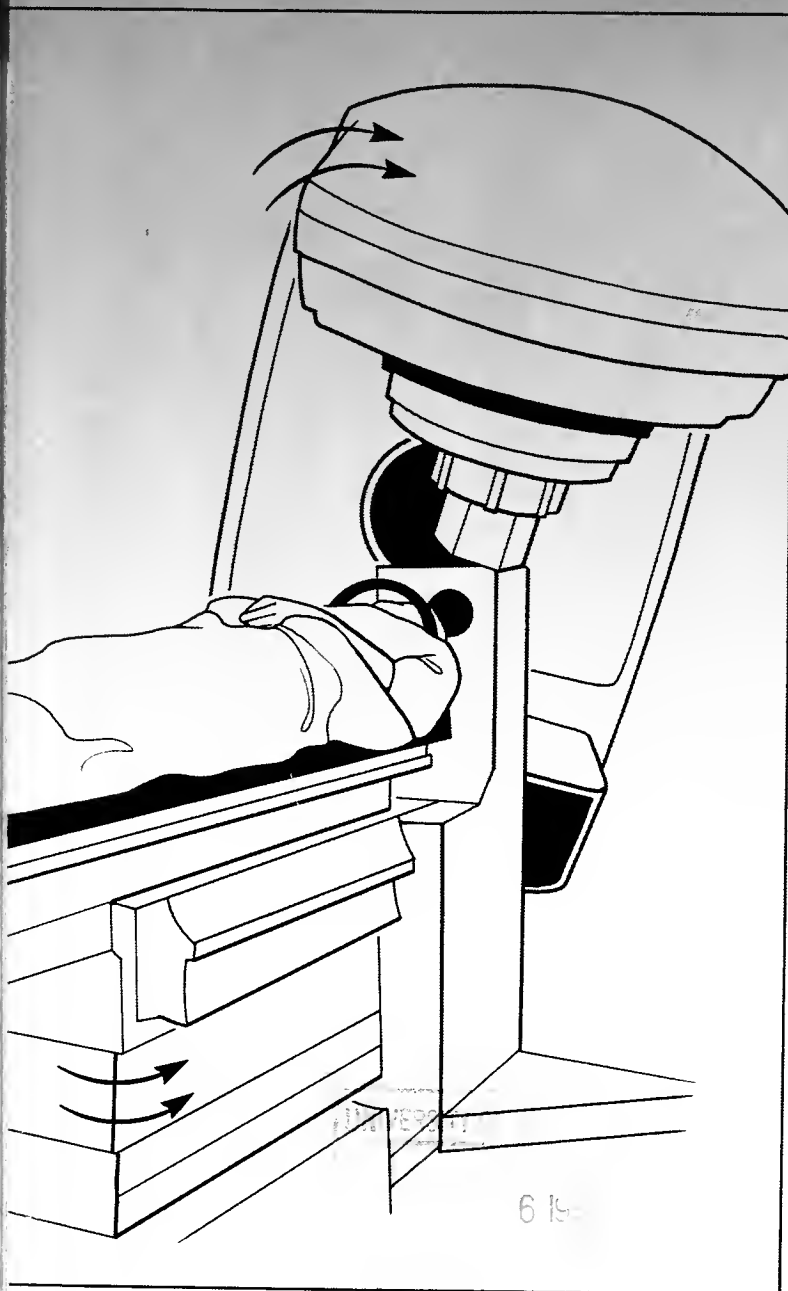
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The
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August 1992
Volume 53
Number 8

North Carolina Medical Journal

For Doctors and their Patients



Stereotactic Radiosurgery:

**A Review of "Gamma
Knife" and "Linac Knife"
Technology and the
Unit at the Wake Forest
University Medical Center**

by C.L. Branch, Jr., M.D., D. Coric, M.D.,
W. Olds, M.D., and K. Ekskstrand, Ph.D.

Also in this issue:

**The Content of One Doctor's
Practice: Relevance of the
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**Health Watch:
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**Reproductive Health:
Detection of Sexually
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North Carolina Medical Journal

FOR DOCTORS AND THEIR PATIENTS

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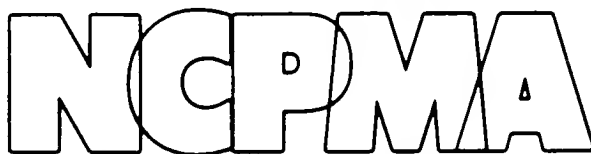
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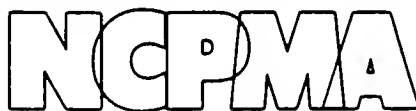


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Letters to the Editor

A Drug Story

To the Editor:

Mrs. H. came to clinic on the second anniversary of the replacement of her aortic valve for aortic sclerosis/stenosis. She has been doing well, graduating from the cardiac rehabilitation program, walking four miles each day without shortness of breath or chest pain, and using Atenolol and Coumadin as her only medications. She had just reached her 65th birthday, and she had no clear understanding of her health insurance coverage. Her prothrombin time had been easily controlled on 10 mg of Coumadin/day. She purchases her drugs at the hospital pharmacy.

Most of the conversation in the clinic concerned the marked difference in price paid for Coumadin. A bottle of 100 tablets purchased in November 1991 cost \$5.85; a bottle of 100 tablets in March 1992, \$85.40. These charges were confirmed by the pharmacy. What happened?

Pharmacists here at the UNC Hospitals confirmed similar logarithmic increases in costs for other commonly used drugs, such as Premarin and Nitroglycerine patches, making the patient costs "more in line with outside pharmacies." They stated that the phenomenon was due to "Medicaid"—and the changes in their costs took place on January 1, 1992.

How does the patient obtain Coumadin?

Having made the serious decision to use and monitor Coumadin anticoagulation in a particular patient, the physician establishes the dose, educates the patient, arranges follow-up testing, and writes the prescription so that the drug can be obtained by the patient. Most often the patient obtains a short supply from the hospital pharmacy at the time of hospital discharge. The prescription for a long-term supply is usually written separately so that the patient can obtain the drug most economically, taking advantage of,

and assuming, cost-reducing forces such as marketing, competition, and mass distribution (for example, AARP and Health Plan Pharmacies), etc. Hopefully the physician realizes that the cost of the drug to the patient in most instances is the cost of the drug to the pharmacy plus a dispensing fee or mark-up. (Therefore if long-term usage is planned, the relative contribution of the dispensing fee to the total cost is reduced by writing for a three-month supply.)

Senator David Prior (D-AR) sponsored two bills in 1990 (S 2605—Pharmaceutical Anti-Discriminatory Drug Act) that were melded into the budget bill of 1990 (Omnibus Budget Reconciliation Act of 1990), and signed into law on November 5, 1990. These bills required a Medicaid rebate by the manufacturer of a percentage of the "best price" (lowest price paid by any purchaser for the retail class of trade). Prices paid by hospital and HMOs that dispense drugs to outpatients at no more than purchase cost (plus dispensing fees) are exempt; however, prices available to these entities are included in "best price" calculations.

The Byzantine regulations produced by these laws, designed to obtain a "best price" for Medicaid drugs, were quickly understood by the pharmaceutical companies to hinge on "best price" averages. This average could be improved by eliminating any "special price" to entities such as hospitals, thus resulting in an increased average wholesale price with little variation, maximizing total return (and profit). If in addition there is no effective competition (monopoly). There is no relationship between cost to the patient and true cost to the manufacturer.

Why did the charge skyrocket? Willie Sutton would answer, "That's where the money was." Another response could be "what the market could bear." The current "market forces" around Coumadin are complex. Issues such as control of the

market (collusion? monopoly?), usual practice, and necessity, as well as competition, destruction, and availability all play a role. The "cost containment" efforts by the government as well as third-party reimbursors affect patients and their out-of-pocket costs. Physicians, in turn, are involved as they try to help overcome the financial barriers by filling out reimbursement papers and/or writing extra prescriptions for the patient to employ in finding the "best buy."

Coumadin, which has been in the marketplace for almost 50 years (no longer covered by patent; it is currently manufactured exclusively by DuPont. No generic formulation is available. Our medical community uses this drug for the pharmacologic reduction of the Vitamin K dependent clotting factors exclusively, instead of the alternative, Dicumarol, hence giving the DuPont company a monopoly. The price of Coumadin here, however, is no greater (or less) than that available for mail order services.

The marked increase in cost to my patient occurred because the price formerly charged to my hospital pharmacy was elevated to the general market price, in order for the average price figures for the DuPont Company to be uniform and therefore produce a better "best price" for the Medicaid-mandated reimbursement.

Whether or not mandating and manipulating thorough legislation will ever help make drugs affordable (to whom ever pays) seems to be very questionable. In my patient's case it led to much activity on her part seeking the best price, some activity on my part (writing extra prescriptions so that comparative shopping could occur), and a feeling of dismay at the complexity and cost of getting an old, necessary medicine to my patient.

James A. Bryan II, M.D.
UNC School of Medicine
CB #7110, 5039 Old Clinic Bldg.
Chapel Hill, NC 27598-7110

Patient Hair Loss

To the Editor:

I saw a 58-year-old female who had been taking Seldane for her nose allergy. Her hair began falling out by the "handfuls." Six weeks after stopping the Seldane, her hair stopped falling out. Has anyone else had this experience with a patient?

The PDR gives alopecia as a possible adverse reaction to Seldane.

Claude A. Frazier, M.D.
Doctors Park, Bldg. 4
Asheville, NC 28801

A Response for Dr. Frazier:

The description of hair coming out by the "handfuls" in this patient, presumably all over the scalp since the examining physician does not note a patchy distribution of hair loss, indicates that this is most likely a telogen effluvium. Telogen effluvium is a descriptive term indicating increased shedding of an abnormal amount, generally >100/day, of telogen or "resting" hairs. An increased percentage of telogen hairs may occur in any situation where there is physical or emotional stress, nutritional deficiency (either caloric or protein), hormonal aberrations or fluctuations, or anemia. A telogen effluvium may also be the first sign of a diffuse pattern of alopecia areata, but this would eventually show up as "balding" versus "thinning," something not described in this patient.

Certain drugs cause a telogen effluvium in a high percentage (>5%) of patients; these include beta-blockers, anticoagulants (Heparin or Coumadin), lithium, valproic acid, methotrexate (psoriasis or rheumatoid arthritis doses of 15 to 25 mg/wk), interferon, and retinoids/superphysiologic doses of Vitamin A. Other drugs reported to cause hair loss include NSAID, phenothiazines carbamazepine, fluoxetine, clomiphene, allopurinol, amphetamines, levodopa, bromocriptine, penicillamine, tricyclic antidepressants, angiotensin converting enzyme (ACE) inhibitors, and cimetidine.

Androgens such as anabolic steroids, Danazol, or androgenic progestins such as Norgestrel may mimic a telogen efflu-

vium in women with androgenetic alopecia, but close inspection of the scalp will indicate that the hair loss is usually accentuated on the top of the head. Antithyroid drugs regularly cause alopecia, but this may be at least partially related to the induced hypothyroid state. It must be emphasized that any drug may cause hair loss in an individual patient, analogous to a hypersensitivity reaction. This includes a drug a patient has been on for a long period of time without a prior problem.

A good history and physical examination in the case of Dr. Frazier's patient will eliminate most of the potential causes of telogen effluvium noted above. Presuming that the patient had none of the above noted potential causes of hair loss and a normal blood count and thyroid profile (a minimal laboratory screen in these patients) we can then and only then address whether Seldane is a potential source of her hair loss. Drug-related hair loss is a diagnosis of exclusion.

Seldane or Terfenadine is a piperidine antihistamine. There has been one published report of a patient with hair loss while on terfenadine, with regrowth off drug and recurrence on rechallenge. Alopecia was not noted in any of 12,000 patients participating in clinical trials of Seldane (active drug or placebo), but has been reported at a rate of 2/1,000,000 patient-months of use since foreign sales began in 1981 and domestic sales in 1985. The only certain way to tell whether a drug is causing hair loss is to stop the drug, wait until a normal density of hair growth resumes (usually six to 12 months) and rechallenge with the drug. Usually hair loss occurs three to four months after an inciting event, the time it takes for an anagen hair to shut down production and move several millimeters superficially up in the dermis to become a poorly anchored, easily shed telogen hair.

At this point, the evidence for Seldane causing the hair loss is possible, but could be considered definite only after further information and follow-up.

Elise A. Olsen, M.D.
Associate Professor of Medicine
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Half-Empty or Half-Full?: Two Responses to "Elegy"

To the Editor:

Dr. Hathaway's letter ("Elegy for a Way of Life," by Harvey Hathaway, M.D., NC Med J 1992;300-4) was a golden lament of an era in transition. The deans who commented (Janeway, Graham, Hallock, Bondurant) carried well their constant duty to look to the future and try to create there the best that they may.

I wonder if our deans are consistently courageous enough to remind their students that the essence of their social contract with patients is to put the patients' interests ahead of their own? That's a tough requirement, but that is what creates the kind of relationship, the passage of which Dr. Hathaway laments. Unfortunately, although that contract justifies the physicians' "nice living," it cannot be paid for with money, but only with the returned affection and respect of patients and their families. It is the emotional warm strokes of medicine that allow it to be such a "jealous mistress," and it is those warm strokes that are so endangered by today's reimbursement schemes as well as those projected for tomorrow.

Whoever pays the bills is the boss. When that boss is an outsider with an independent economic interest and is intruding into this relationship, it moves to the brink of destruction. Politicians want credit for "taking care" of their constituents, and they have bought a slice of this relationship with the taxpayers' money. Having practiced before Medicare, I can witness that this has not greatly increased "access." And I doubt that such institutions as Charity Hospital in New Orleans or Cook County Hospital in Chicago find themselves serving their people more gracefully today than 30 years ago.

I find "the concept of shared autonomy" an ambiguous subterfuge for an effort to require physicians to remain responsible for their patient's care without retaining the authority to effect it. I find it much easier to practice medicine in an atmosphere of shared responsibility with my patients, but this, for me, has always been so and grows directly out of our relationship and not from the interference of relatively ignorant third parties whose sustenance is leached from this relationship.

I think it was Dr. Bondurant who once wrote about the continuing role of the physician as an interface between patients and the science of medicine. That security and the excitement of new technologies are the bright lights for the next generation of physicians.

When medicine was an art, it was also an avocation; now that it is a science, it is also a career; when it is a civil service, it will also be a bore. That would be a terrible shame indeed. Let us hope that we may still shine the "beautiful light."

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To the Editor:

My immediate reaction to "Elegy for a Way of Life" by Dr. Hathaway (NC Med J 1992;300-4) was anger. After reading the article again, I can only feel sorry for Harvey. He has lost "it," he has given up, or perhaps, he never had "it." When the going got tough, he simply could not adjust to the changes in medicine of the past 20 years. Part of Dr. Hathaway's problem is that he believed he could carry on the traditions of his father. What he failed to understand is that early 20th-century medicine is no longer good medicine.

Dr. Hathaway bemoans managed care, malpractice concerns, government regulation, and intrusion. Many of these current realities in medicine were created by the pseudo-culture of the "Magnificent Deity" who anticipated that His patients (certainly He never considered them consumers) would blindly accept what-

ever the doctor ordered. How many times have the mores and private standards of such physicians controlled the level of care—penicillin shot for a viral cold, Vitamin B12 shot for energy, no birth control for unmarried females. These are the doctors whose values were such that medical incompetence or unfitness was ignored or covered up. Many of today's harsh realities in the practice of medicine stem from these very practices. Is this the "Way of Life" that Dr. Hathaway would propose to promulgate?

Yes, Medicine has changed. What happens, however, if those of us with education, knowledge, experience, and skill simply acquiesce? We cannot afford to give up, get depressed, or bemoan our fates every time some bureaucrat creates another series of rules. Virtually every physician with whom I have talked recently believes, for example, that the OSHA regulations epitomize the worst of government regulations. Does that mean we quit? In addition to OSHA, consider the demands of managed care, the absurdities of practicing defensive medicine, and the sheer expense of practice management. No, these are not Dr. Hathaway's "good old days."

I believe that the new physicians of today do not have Dr. Hathaway's attitude nor, most importantly, will they in 20 years. They will come to us highly skilled and will demand quality care. This skill level and their demands will only support the necessary growth that the next years will bring.

Frankly, I believe Dr. Hathaway should quit feeling sorry for himself. He must face *today's* realities. The specialty of obstetrics and gynecology is one of the most exciting in medicine. Eighty-five percent of all women get into the health care system through an ob-gyn. Consider this direct impact on women and the indirect impact on their families. Keeping families healthy keeps families healthy.

There are problems—never enough time with the family, daily fights for reimbursement, medical politics that control women's reproductive lives, ever-increasing practice expenses. As for me,

I would gladly do it all again. And I would do it even more willingly since today's physician can do so much more because there are a multitude of allied health professionals, resources, and just plain damned good technology that assures we can do things for our patients that were science fiction a few years ago.

In summary, I empathize with Dr. Hathaway as a human being. I am not, however, empathic with the individual who enters our profession and decades later is wondering where are the good old days. I am sure both Dr. Hathaway were good doctors. What makes Dr. Hathaway's expectations of medicine today inappropriate is that he apparently had no expectation of change or development. That certain change and development is what continues to excite me and my colleagues who still proudly call ourselves physician.

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The Philosophy of Medicine

To the Editor:

I so enjoyed "Doctors Who Write" by James R.B. Nashold, M.D. (NC Med J 1992;53;205-9). It was such a treat to read an article dealing with the philosophy of medicine as opposed to the facts of medicine. The article was informative, thought-provoking, and above all very enjoyable.

One rarely sees this side of medicine addressed in print, and yet I feel today more than ever that the ideas mentioned in the article are pertinent and important. The article encourages one to focus on the patient as a person as opposed to the patient as a problem. I personally feel this is all important in trying to get to the bottom of a patient's problem and ultimately in treating the patient.

What a breath of fresh air and what a joy after endless articles about the day to day hassles of modern-day delivery of medical care, i.e., R.B.V.S. reform, Medicare, PRO, legal issues, etc. The

article brightened my day and cheered up my spirit. I think gentle reminders and prompters of things we can be doing for our patient above and beyond codes, numbers, procedures, etc. are needed. What a joy!

Once again, thanks to the *Journal* for addressing this side of medicine. It was very much appreciated.

Georgia L. Newsom, M.D.
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Sylva, NC 28779

For the Record

To the Editor:

I am writing to correct a grave injustice to the reputation of the late Dr. Isaac Manning, who was dean of the two-year medical school of the University of North Carolina in the early 1930s.

In the second part of his *Carolina History*, ("Alien Corn in the Big Apple Part II," NC Med J 1992;53:33-40) John Borden Graham, M.D., states, "Dean Isaac Manning of the University of North Carolina had resigned in 1932 rather than admit a Jewish student from Brooklyn."

Dr. Graham's reference to anti-Semitism in the field of medical education is entirely correct since the enrollment of Jewish students was pretty much generally restricted to 10% of the student body. However, Dr. Manning did not admit the student in question noted above just because he already had a Jewish enrollment of 10%. Over the years he had developed relationships with four-year medical schools, which "guaranteed" him the ability to transfer a Jewish student to one of these after successful completion of the two-year curriculum at Carolina. This permitted him to assure transfer for each of the four students already enrolled. Dr. Manning was a man of great honesty and character, and he felt it would be entirely dishonest to take a fifth Jewish student into the class, one for whom he could not assure transfer at the completion of the two-year curriculum.

Dr. Frank P. Graham and Dr. Manning disagreed on this matter, and ultimately, Dr. Manning, in support of his principles, did indeed resign prior to 1934,

when I fortunately was one of the four students admitted by Dr. Mangum, the subsequent dean.

Otto S. Steinreich, M.D.
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Manuscript Review

To the Editor:

I have just read "Reading, 'Riting, Peer Reviewing" (NC Med J 1992; 53:264-5) and am responding to your invitation to add my name to your list of potential reviewers for the *Journal*. My clinical interests are hematology and oncology. As a faculty member, I am vitally interested in medical education at all levels and matters pertaining thereto. Also, I have a special interest in geriatrics in connection with certain responsibilities I have assumed, including medical directorship of a large nursing home.

If I can be of service to the *Journal* by reviewing submissions for publication, especially in the above areas, I will be glad to do so.

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Questions Peer Review

To the Editor:

As you know, from the first, I have questioned the utility (and the behavior) of the federally mandated Peer Review System as being an empty exercise. The May 6, 1992, issue of *JAMA* (see Rubin HR, Rogers WH, Kahn KL, et al, "Watching the Doctor-Watchers") confirms this lack of worth, which costs the taxpayer directly and the system indirectly a huge amount of money.

Is it not time to lead an effort to stop this resource drain? Does the current local Peer Review organization (MRNC) receive its legitimacy from the state Medical Society or is it an independent, self-perpetuating embodiment of

Parkinson's law? As far as I can tell the MRNC has never clearly articulated its mission, measured its effectiveness, or accounted for its cost.

I would like to know the involvement of the Medical Society in MRNC and what, if any, accountability the Medical Review of North Carolina has to the Society.

I hope to interest my Congressman in having the "federal mandate" reviewed and removed to eliminate this waste.

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From the Editor:

Since we received letters for this issue regarding medical peer review and manuscript peer review, the difference between them should be noted. We forward manuscripts to physicians to evaluate their worthiness for publication (see Reading, 'Riting, Peer Reviewing," NC Med J 1992;53:264-5). Dr. Bryan is referring to a form of medical audit, called peer review, carried out by peer review organizations (also called professional review organizations, or PROs).

NCMS President Dr. John T. Dees and Dr. Rodney Hornbake, who leads the Society's PRO focus group, wrote to Dr. Bryan to explain that the MRNC is not formally accountable to the Medical Society but that they have been open to discussions with the Society's PRO focus group.

The *North Carolina Medical Journal* encourages feedback from its readers in the Letters to the Editor column. All letters must be typed, double-spaced, signed, dated, and include the author's phone number and address.

The *Journal* reserves the right to edit or condense letters for length, clarity, and style, and to withhold letters based on the editor's discretion. Send submissions to: Letters to the Editor, *North Carolina Medical Journal*, Box 3910, Duke University Medical Center, Durham, NC 27710; fax: 919-286-9219.

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Blank space indicates that no such activity has been reported. Table adapted from Facts and Comparisons 1991 and Catalano RB. The medical approach to management of pain caused by cancer. *Semin. Oncol.* 1975; 2: 379-92 and Reuler JB, et. al. The chronic pain syndrome: misconceptions and management. *Ann. Intern. Med.* 1980 588-96.

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Furthermore, narcotics produce adverse reactions which may obscure the clinical course of patients with head injuries. **Acute Abdominal Conditions:** The administration of narcotics may obscure the diagnosis or clinical course of patients with acute abdominal conditions. **PRECAUTIONS:** Special Risk Patients: VICODIN/VICODIN ES Tablets should be used with caution in elderly or debilitated patients and those with severe impairment of hepatic or renal function, hypothyroidism, Addison's disease, prostatic hypertrophy or urethral stricture. Cough Reflex: Hydrocodone suppresses the cough reflex; as with all narcotics, caution should be exercised when VICODIN/VICODIN ES Tablets are used postoperatively and in patients with pulmonary disease. **Drug Interactions:** Patients receiving other narcotic analgesics, antipsychotics, anxiolytic agents, or other CNS depressants (including alcohol) concomitantly with VICODIN/VICODIN ES Tablets may exhibit an additive CNS depression. The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus. **Use in Pregnancy:** Teratogenic Effects: Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN/VICODIN ES Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic effects:** Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. 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These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include: **Central Nervous System:** Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence and mood changes. **Gastrointestinal System:** The antemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur (see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of VICODIN/VICODIN ES Tablets may produce constipation. **Genitourinary System:** Urteral spasm, spasm of vesical sphincters and urinary retention have been reported. **Respiratory Depression:** Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated. **DRUG ABUSE AND DEPENDENCE:** VICODIN/VICODIN ES Tablets are subject to the Federal Controlled Substance Act (Schedule III). 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Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. **Hydrocodone Signs and Symptoms:** Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdose, apnea, circulatory collapse, cardiac rest and death may occur.

Revised March 1992

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Stereotactic Radiosurgery

A Review of "Gamma Knife" and "Linac Knife" Technology And the Unit at the Wake Forest University Medical Center

C.L. Branch, Jr., M.D., D. Coric, M.D., W. Olds, M.D., and K. Ekskstrand, Ph.D.

Stereotactic radiosurgery is a combined neurosurgical and radiation therapy modality that delivers very high doses of ionizing radiation to small, precisely localized intracranial targets. The hallmark of stereotactic radiosurgery is the establishment of a steep dose gradient at the periphery of the particularly radiosensitive target so that surrounding normal brain tissue receives minimal radiation. It permits noninvasive treatment of otherwise inaccessible lesions in a quick and precise manner with low morbidity and mortality. Stereotactic radiosurgery is a multidisciplinary procedure that requires the cooperative interaction of several specialists: 1) a neurosurgeon; 2) a radiation oncologist; 3) a radiation physicist; and 4) a neuroradiologist.

Background

In 1951, the Swedish neurosurgeon Lars Leksell pioneered the technique of stereotactic radiosurgery. Leksell combined a stereotactic guiding device with a radiotherapeutic modality to provide noninvasive treatment of intracranial lesions that were located in poorly accessible or particularly sensitive regions of the brain.¹ Leksell coined the term radio-

surgery to accentuate the differences between this procedure and conventional radiation therapy. Radiation therapy generally irradiates large areas of the brain, relying on the biological differences in radiosensitivity between tumor cells and normal cells to achieve its effect. In contrast, radiosurgery utilizes a beam of radiation as a surgical tool for the precise destruction of tissue in a small, well-defined area.

Leksell's original technique used x-rays from a standard source, which were narrowed into thin beams by an adjustable collimator. The intracranial target was placed at the center of a semicircular arc and the narrow beams of ionizing radiation were cross-fired at the target from multiple points on the arc. This technique was abandoned due to the difficulty in maintaining accurate aim during rotation of the x-ray source. Over the next decade, others modified the procedure to use proton beams as the radiation source. These beams consist of heavy, charged particles generated by a synchrocyclotron.² This type of radiosurgery first became available in the United States in the late 1950s at Cambridge, Massachusetts, and Berkeley, California.

In 1968, Leksell, working with Larsson, designed and implemented the first

"gamma knife" radiosurgical unit.³ This unit utilized gamma rays derived from cobalt-60 as its radiation source. In 1987, a "gamma knife" unit in the United States for routine use in the treatment of patients became operational at the University of Pittsburgh.⁴

The latest modification was the development of instrumentation that allowed a linear accelerator (linac) to be rotated around the target with great accuracy. Now, the standard linear accelerators used in conventional radiotherapy can be adapted very accurately for use in radiosurgery.⁵

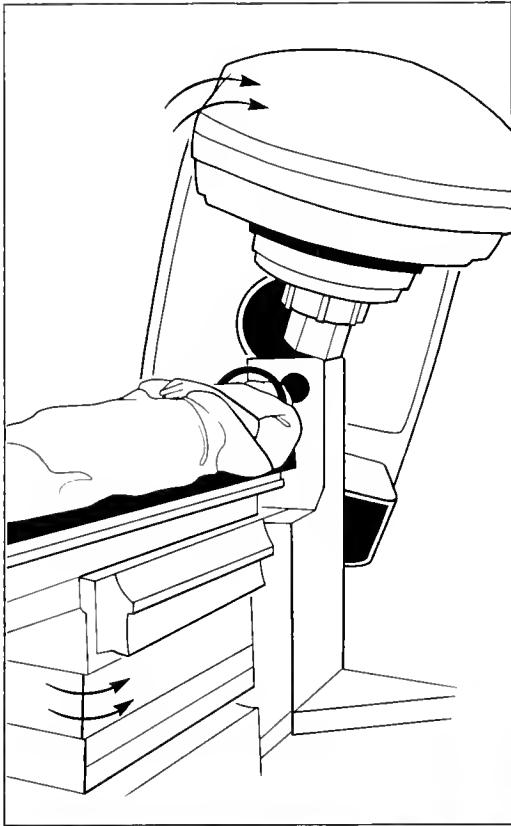
Radiation Source

All radiosurgical procedures require the delivery of a single, high dose of ionizing radiation to a small, stereotactically localized intracranial target. Currently, there are three basic systems available for stereotactic radiosurgery (Table 1), each

Table 1. Stereotactic Radiosurgical Systems

Radiation source	Ionizing radiation
1) Cyclotron	Heavy particle beams (protons, neutrons)
2) Radioactive cobalt-60 (gamma knife)	Gamma rays (photons)
3) Linear accelerator (linac knife)	X-rays (photons)

From the Departments of Neurosurgery and Radiology (Radiation Oncology), Bowman Gray School of Medicine, Wake Forest University, Medical Center Boulevard, Winston-Salem, NC 27157.



utilizing a different radiation source: 1) cyclotrons—which emit beams of heavy charged particles (protons, neutrons, helium ions, and other charged particles); 2) the “gamma knife”—which utilizes a radioactive isotope (cobalt-60) to produce photons (gamma rays); and 3) linear accelerators—which generate electrically produced photons (x-rays). Since both x-rays and gamma rays are photons, in general terms the major difference between these last two systems is the radiation source.⁶

Cyclotrons use heavy particle beams to take advantage of the “Bragg-peak” phenomenon. Heavy charged particles lose energy uniformly along their path until they reach the end of their range where they predictably and dramatically increase their energy loss to deposit the maximal dose. The depth at which the Bragg-peak occurs can be adjusted with absorbers to match the target size.⁷ Despite this theoretical advantage, the widespread use of cyclotrons is precluded by their cost (up to \$50 million), their cumbersome size, and their complexity, requiring large numbers of operating personnel. A lower-priced neutron unit that may be used to generate protons is currently being installed at the University of Washington in Seattle, but the availability of this technique is still limited to relatively few centers.⁶

The “gamma knife” was designed specifically for radiosurgery and, compared to the cyclotron unit, is relatively simple to use. It has been used with success⁸ to treat numerous neurosurgical lesions over

the past 20 years, but logistical considerations do impose major limitations on its availability. The relatively short half-life of cobalt (5.26 years) necessitates replacement of the radiation source every seven to 10 years. Additionally, the radioactive cobalt requires extensive shielding. Currently available gamma units may require extensive site preparation. Finally, they cannot be adapted for uses other than stereotactic radiosurgery. Therefore, installation of gamma units is probably not cost-effective except in medical centers with a large referral base or where a large population of patients with treatable lesions can justify the costs.⁶

Currently, the linear accelerator is the most widely used method for delivering radiosurgery. Most large hospitals have at least one linear accelerator to deliver conventional radiation therapy. These standard accelerators can be modified for use in both radiosurgery and standard radiation therapy. Furthermore, linac units contain no radioactive isotopes. Due to the wide accessibility and cost efficiency of these units, numerous radiosurgical systems have been developed using them as the radiation source. Linac-based radiosurgical systems utilize multiple arcs of radiation with changes in head position between arcs or by simultaneous rotation of the gantry. The result is multiple intersecting beams of radiation, all focused on the stereotactically localized target (Figure 1).⁹

The stereotactic radiosurgery program at the Wake Forest University Medical Center in Winston-Salem uses a Philips SRS-200 stereotactic radiosurgery system with a 6 MeV linear accelerator. A stereotactic apparatus, a modification of the Brown-Roberts-Wells (BRW) system, is used for treatment planning and to position the patient's head precisely in relation to the radiation beam (Figure 2). A computer program is used to calculate the three-dimensional dose distribution around the target isocenter. Specially designed collimators couple the radiation beam to the stereotactic device¹⁰ producing circular beams between 10 mm to 32 mm in diameter in 2-mm intervals.



Figure 1 (top): Schematic drawing of linear accelerator used for stereotactic radiosurgery. Arrows indicate the axes of rotation of the gantry and the table. **Figure 2 (bottom):** Patient's head fixed in the BRW head ring for delivery of radiosurgery.

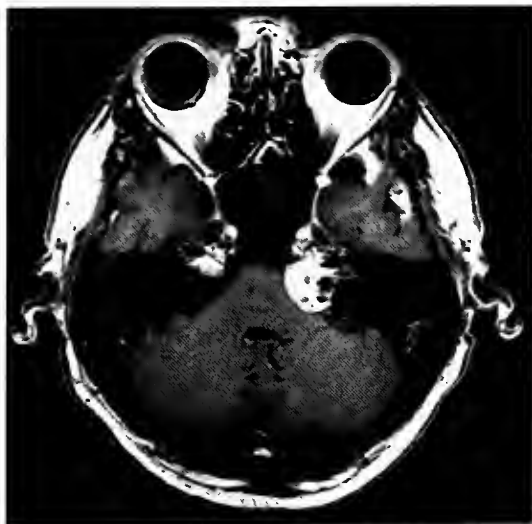


Figure 3: MRI scan of 2.9 cm left cerebropontine angle acoustic neuroma in a patient with vertigo and progressive hearing loss. Following stereotactic radiosurgery (18 Gy to 80% isodose line), the patient showed symptomatic improvement.

Steps in Stereotactic Radiosurgery

The procedure can be visualized as taking place in three distinct phases. The first phase involves localizing the intracranial target. The BRW head ring is mounted on the patient's head with sterile pins, and an imaging procedure, typically computed tomography (CT), or angiography, or both is performed with a localizer head frame attached to the BRW ring. Targets can be localized with an accuracy of 2 mm by CT and 1 mm by angiography.^{5,9} The localization phase can be completed in as few as 40 minutes for CT alone, but can take up to two hours for both CT and angiography.

The second phase consists of treatment planning. The neurosurgeon identifies and outlines the lesion(s) to be treated and the computer generates the target isocenter. Once the target isocenter has been

determined, the localization data are transferred to the computer dosimetry planning system, and the radiation therapist, the physicist, and the neurosurgeon complete dosimetry planning by manipulating collimator size, number of arcs, arc weights, and arcing planes and angles. This phase does not require patient participation and its duration can vary from one to several hours, depending on the characteristics of the lesion and the complexity of the proposed treatment.

The final phase involves the actual delivery of the calculated dose of ionizing radiation. Radiation is delivered using multiple arcs (from 4 to 16) that intersect the computed isocenter. The standard treat-

ment produces a spherical treatment volume, but irregularly shaped lesions can be treated by using multiple isocenters with varying collimators. Depending on the number of isocenters used the radiation treatment lasts from 40 to 60 minutes. Once the dose has been delivered, the head frame is removed and the patient generally is able to leave the hospital within an hour or two; occasionally, overnight observation is required.

Indications for Radiosurgery

Stereotactic radiosurgery offers a novel approach to the treatment of various intracranial lesions. Due to its high dose gradient and precise targeting, radiosurgery can be used to treat small lesions in relatively inaccessible regions of the brain (Figure 3), including lesions in particularly sensitive areas and lesions deep within the brain. Because radiosurgery is noninvasive, there is no anesthetic or operative risk.

Radiosurgery may be considered for patients with brain lesions that are small (generally less than 4 cm to 5 cm in greatest diameter), are found in locations that preclude safe surgical resection, and are well visualized on appropriate neuroimaging studies. In selected cases, a patient with a resectable lesion who refuses conventional surgery or has a medical contraindication to other forms of treatment may be considered for radiosurgery. A list of potentially appropriate conditions might include: arteriovenous malformation (AVM), acoustic neuroma, skull-base meningioma, metastatic brain tumor, malignant glioma, craniopharyngioma, and pituitary adenoma.^{6,11}

An AVM is considered for radiosurgery if its location precludes safe, surgical resection (Figure 4). A small residual

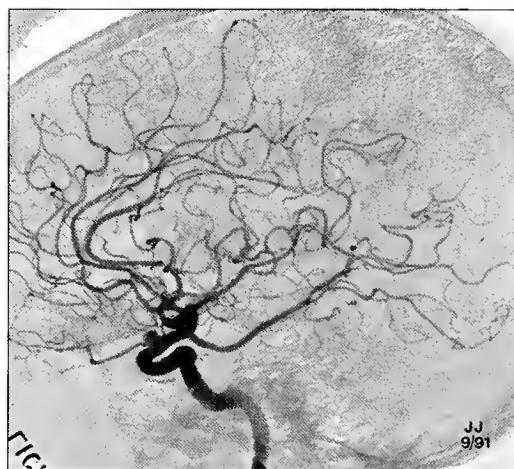
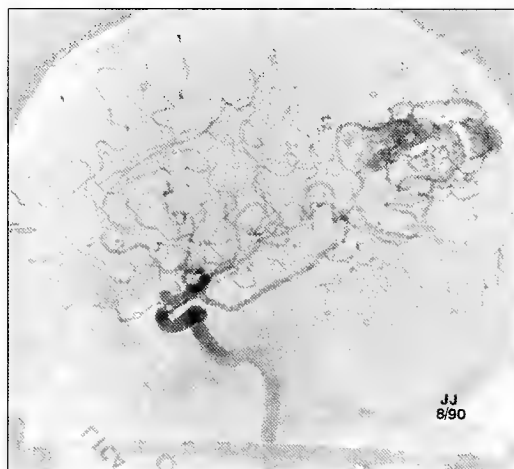


Figure 4: Left—Lateral internal carotid angiogram demonstrates a left parietal occipital arteriovenous malformation in a patient with seizures and persistent headaches. Blindness in one eye precluded safe surgical resection in this occipital AVM. Right—Repeat angiogram 12 months after stereotactic radiosurgery (20 Gy dose to 80% isodose line) demonstrates complete obliteration of the AVM.

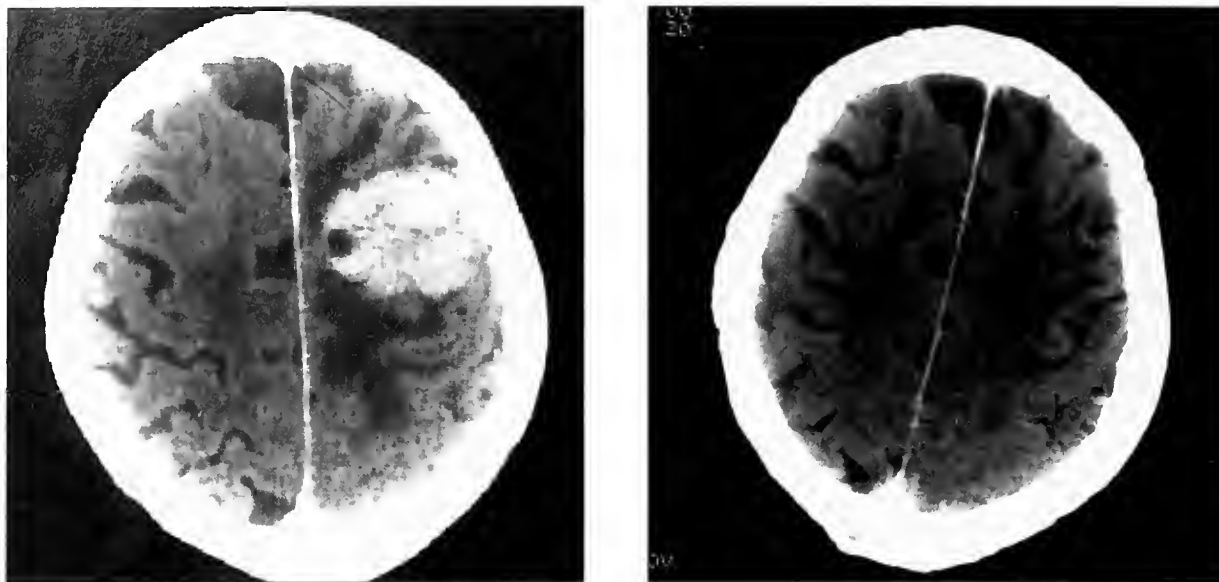


Figure 5: **Left**—Preoperative CT scan of 3.2 cm recurrent small cell carcinoma metastatic to the left parietal lobe in a patient with a progressive right hemiparesis. **Right**—Follow-up scan 3 months after radiosurgery (18 Gy dose to 80% isodose line), shows dramatic decrease in lesion size. The patient's hemiparesis resolved, with return of function.

AVM remaining after attempted surgical resection or other interventional therapy may be successfully treated with radiosurgery. Extensive, hemispheric AVMs are not considered unless or until their size has first been diminished by other techniques. One year after treatment, 80% to 90% of appropriately selected AVMs have been successfully obliterated.¹²

Most acoustic neuromas or skull-base meningiomas can be resected or debulked surgically with relative safety, depending on their size and location. Medical contraindications to a lengthy surgical procedure preclude this option in some patients, while in others residual tumor is left in order to preserve critical neurologic function.

In these cases, even when the tumors are irregularly-shaped, tumor shrinkage or arrest of further tumor growth may be accomplished with radiosurgery. With careful treatment planning and delivery, significant permanent injury to the adjacent brain stem or cranial nerves has been uncommon.

Metastatic brain tumors, single or multiple, that have recurred after multimodal therapy, may be treated effectively with radiosurgery. Radiosurgical treatment may be considered for tumors 3 cm

or less in greatest diameter that are enlarging or are associated with significant symptoms in a patient whose systemic tumor is stable or unresectable. Arrest of tumor growth or substantial shrinkage with remission of symptoms after radiosurgery has been reported in 90% to 95% of cases.¹³ The potential efficacy of radiosurgery in the initial management of a solitary brain metastasis is being investigated at this institution and elsewhere.¹³

The efficacy of radiosurgery in the treatment of small, circumscribed, recurrent, or residual malignant gliomas continues to be investigated. While apparent arrest or control of local tumor growth rate has been accomplished in some cases, the benefit of radiosurgery for this indication remains uncertain.

In general, pituitary tumors or craniopharyngiomas are seldom considered for radiosurgical therapy. The proximity of these tumors to the optic chiasm and other visual or neuroendocrine structures creates a significant risk of injury even with precisely focused radiosurgical techniques.

It must be emphasized that only a relatively small number of patients fulfill the aforementioned indications for this procedure. To date, stereotactic radiosur-

gery has gained wide acceptance only in the treatment of AVMs and certain benign brain tumors. The efficacy of the procedure in the treatment of primary and metastatic brain tumors is currently being evaluated.¹³

Wake Forest University Medical Center Experience

Physicians at the Bowman Gray School of Medicine and North Carolina Baptist Hospital began to treat patients with stereotactic radiosurgery on August 14, 1990. At the end of one year, 28 patients had been treated. These patients (15 women and 13 men) ranged in age from 20 to 79 years (mean age, 51.3 years). The lesions treated were 13 metastatic tumors, 6 AVMs (4 infratentorial, 2 supratentorial), 6 primary benign brain tumors (3 meningiomas, 3 acoustic neuromas), and 3 primary malignant brain tumors. In largest diameter the lesions ranged from 0.80 cm to 9.35 cm (mean size, 3.29 cm), and treatment isocenters ranged from 1 to 4 in number. Although the response of any given lesion is unpredictable, some responses have been dramatic (Figure 5).

Conclusion

Although the overwhelming majority of patients with intracranial lesions still are best served by conventional neurosurgery or radiation therapy, stereotactic radiosurgery has proved to be a safe, efficacious, and economically prudent alternative in selected patients. As stereotactic radiosurgery becomes more widely available, emphasis must be placed on establishing its specific role in the treatment of intracranial lesions. To date, we have limited our use of this technique to inoperable lesions or those in patients whose medical condition poses an unacceptably high risk for conventional neurosurgery.

We are actively involved in a continuing effort to determine the appropriateness of stereotactic radiosurgery for various other neurosurgical applications. The Bowman Gray School of Medicine has joined Harvard University and the University of California at San Francisco in a collaborative study of the treatment of single brain metastases. This is a randomized, prospective clinical trial comparing the efficacy of radiosurgery to conventional microsurgery in the management of patients with single metastatic lesions to the brain. We also have begun a preliminary clinical trial of combining radiosurgery with various chemotherapeutic agents in the treatment of recurrent malignant gliomas. The pur-

pose of this pilot study is to evaluate the feasibility of utilizing radiosurgery in the aggressive treatment of recurrent primary malignant brain tumors.

For the present we may summarize by saying that technological advances over the past decade have made stereotactic radiosurgery a feasible and accessible modality for treating previously inoperable intracranial lesions. This modality is now recognized as a valuable adjunct to conventional neurosurgical techniques. □

Editor's Note: Stereotactic radiosurgery is now available at several hospitals in North Carolina and at approximately 75 sites nationwide.

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A Woman With Too Much Facial Hair

Evaluating the Possibility of Attenuated 21-Hydroxylase Deficiency in Hirsutism

Doris Iarovici, M.D., and Francis A. Neelon, M.D.

A 47-year-old, overweight woman, gravida 2 para 2, came to us for general evaluation. She complained of hirsutism of longstanding duration. Over the past 16 years she'd noted thinning hair with some hair loss over the frontal areas similar to male pattern balding. She was also troubled by facial hair over the chin, which she shaved, and by mild hypertension. She'd been evaluated three years previously by a dermatologist, who detected elevated levels of dehydroepiandrosterone (DHEA) sulfate, and sent the patient to an endocrinologist. The endocrinologist gave an injection of cosyntropin (synthetic ACTH) and measured the response of 17-hydroxyprogesterone. He interpreted the rise in 17-hydroxyprogesterone as excessive, compatible with a partial 21-hydroxylase deficiency (Figure 1), and she was started on 2.5 mg of prednisone daily.

After a few months on prednisone her DHEA level was found to be within the normal range, but her hirsutism was unchanged. She then saw another doctor, who questioned the diagnosis of 21-hydroxylase deficiency, discontinued the prednisone, and repeated the cosyntropin-stimulation test; this doctor thought the results were normal.

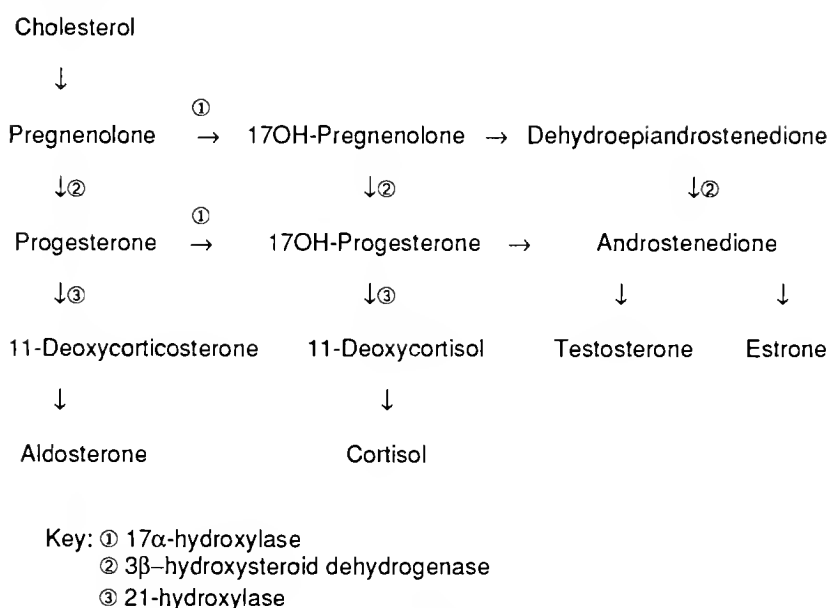
The patient wanted to know whether or not she in fact had a partial 21-hydroxylase deficiency, and if so, how she

could be treated. We decided to review the clinical manifestations of 21-hydroxylase deficiency, paying special attention to the laboratory tests one should order in evaluating hirsute patients for a suspected defect in adrenal steroidogenesis. And we wanted to know, given the conflicting interpretation of her cosyntropin-stimulation tests, whether we could commit a patient to taking a medication (prednisone) for life on the basis of the hormonal response to a single pulse of ACTH.

Attenuated 21-Hydroxylase Deficiency

Hirsutism, which implies abnormal, androgen-dependent hair growth, is a fairly common problem.¹ Excessive facial and body hair growth can be caused by increased sensitivity of hair follicles to normal levels of androgens or by elevated androgen levels. Androgen levels can be elevated either from overproduction by the ovaries or the adrenals, or from increased peripheral conversion of weak

Figure 1: Outline of Steroid Biosynthetic Pathways



Adapted from Ehrmann and Rosenfield¹

From the Department of Medicine, Box 3021, Duke University Medical Center, Durham, NC 27710.

androgens to potent ones. Since adipose tissue is an important site of peripheral steroid conversion, obesity must be included on the list of factors possibly contributing to hirsutism. Because many different causes of hirsutism create identical clinical findings and even similar biochemical abnormalities, they are often difficult to tease apart. Still, most experts feel it is important to establish the correct diagnosis because treatment options differ based on cause.²

Among the causes of adrenal androgen overproduction is a deficiency of 21-hydroxylase, one of several enzymes used by the adrenals to synthesize cortisol and aldosterone (Figure 1). In the classical form of 21-hydroxylase deficiency, the patient inherits an abnormal gene for 21-hydroxylase from each parent.¹ The resulting severe lack of enzyme activity blocks the synthesis of cortisol, causing the diversion of cortisol's precursor, 17-hydroxyprogesterone, into the androgen androstenedione and thereby virilizing female infants. In the most severe forms of 21-hydroxylase deficiency, there is a lack of mineralocorticoids leading to salt-wasting in infants of both sexes. Because this metabolic disturbance can be life-threatening, it makes its presence known early in life.

If patients have milder defects in enzymatic activity, an "attenuated" form of the disorder occurs. The increase in androgen production is not severe enough to masculinize female genitalia, but at puberty there is a change in adrenal androgen production and a mild virilization begins in females.³ Also known as late-onset adrenal hyperplasia, this syndrome can present in many different ways and is often confused with polycystic ovary syndrome.^{3-5,7} Both cause hair loss over the scalp, hair growth over the face, abdomen, and thighs, and menstrual irregularities, and both can be accompanied by cystic ovaries. In the general population, the prevalence of late-onset 21-hydroxylase deficiency is unknown.² In hyperandrogenic hirsute women, 6% to 12% of cases are due to attenuated 21-hydroxylase deficiency.^{5,7} While deficiencies of other enzymes of steroido-

genesis, such as 11 β -hydroxylase and 3 β -hydroxysteroid dehydrogenase, can cause hirsutism, 21-hydroxylase deficiency is the most common abnormality.⁷

Diagnosis: The Cosyntropin- Stimulation Test

Since the clinical abnormalities in attenuated 21-hydroxylase deficiency are caused by increased synthesis of androgens, it seems reasonable to expect elevated levels of testosterone or DHEA. This is generally not the case. Androstenedione, a testosterone precursor, was elevated in one study, but testosterone remained mostly normal.⁴ Other studies have found plasma-free testosterone slightly increased, but concluded that the episodic secretion of androgens makes any single measurement unreliable.¹ Nevertheless, some experts have recommended giving low-dose dexamethasone for five days, and interpret a decline in androgen levels as indicating an adrenal disorder (these low doses of dexamethasone should not affect levels secreted by the ovaries).¹ However, this is time-consuming, and still requires the patient to undergo further tests to pin down a diagnosis.

The consensus favors using the cosyntropin-stimulation test to establish the diagnosis.¹⁻⁶ Most studies use 1 mg of cosyntropin, though doses ranging from 0.1 mg to 1 mg provide similar results.⁵ Thirty minutes after an intravenous bolus of cosyntropin, the 17-hydroxyprogesterone in women with attenuated 21-hydroxylase deficiency rises dramatically. Sometimes there is as much as a ten-fold rise over a baseline that may be normal or slightly elevated. Post-stimulation concentrations of 17-hydroxyprogesterone reaching the low thousands in ng/dL.⁶ There are caveats as to how the testing must be done. The response is much more obvious when the test is performed during the follicular phase of the menstrual cycle,^{5,6} since the ovaries increase their progesterone output during the luteal phase, confusing matters. In oligo-

menorrheic women, tests should be performed when serum progesterone is less than 8.0 nMol/L (2.5 ng/dL). For uniformity of results, the test is best done in fasting women in the morning (8 a.m.-10 a.m.), since ACTH fluctuates during the day. And special care must be given to the way in which results are recorded. Different labs use different units, and confusion arises trying to relate a patient's values to published studies.

Although most experts recommend recording baseline and post-stimulation results, some recommend only a single measurement of 17-hydroxyprogesterone 30 minutes after cosyntropin stimulation.⁵ In one study, a single measure was as efficacious as measuring pre- and post-cosyntropin levels and was easier and more cost effective. But other work suggests the magnitude of the rise from baseline is what makes the diagnosis.² In the case of our patient, an elevated DHEA level led to the decision to perform a cosyntropin-stimulation test. However, this was probably a "red herring" since basal DHEA levels have not been found to be correlated with subsequent diagnoses of 21-hydroxylase deficiency nor do they predict responses to cosyntropin stimulation.² Because it is impossible to differentiate 21-hydroxylase deficiency from other causes of hirsutism on clinical grounds alone, it seems reasonable to recommend that all women in whom no other cause for hirsutism is easily demonstrated should have a cosyntropin-stimulation test. No measurement of baseline hormones can predict which women will be diagnosed with 21-hydroxylase deficiency, but measurement of testosterone and other androgens should be done to exclude other serious problems, such as ovarian neoplasms.

In the case of our patient, the laboratory values of her cosyntropin-stimulation tests turned out to have been misrecorded on both occasions (Table 1). When the correct values were obtained from the laboratory, converted into nanomoles/L and compared to published results in women with attenuated 21-hydroxylase deficiency, it became clear that, although on the first test she did in

Table 1: Our Patient's Cosyntropin-Stimulation Test Results

	Pre-Cosyntropin	Post-Cosyntropin
1st test (as recorded)*	0.2 mcg/dL (6.1 nMol/L)	2.1 mcg/dL (63.6 nMol/L)
1st test (actual results)	0.2 ng/mL (0.6 nMol/L)	2.1 ng/mL (6.4 nMol/L)
2nd test (as recorded)*	0.2 ng/dL (.006 nMol/L)	1.5 ng/dL (0.045 nMol/L)
2nd test (actual results)	0.2 ng/mL (0.6 nMol/L)	1.5 ng/mL (4.5 nMol/L)

*Results were erroneously recorded in the chart in both tests. Numbers in parentheses give the equivalent of the recorded and actual values in nMol/L.

fact have a ten-fold rise in 17-hydroxyprogesterone, the magnitude of the change was still lower than that usually seen in women with 21-hydroxylase deficiency. Furthermore, on the second test, her 17-hydroxyprogesterone rose less than ten-fold and again the actual concentrations of 17-hydroxyprogesterone were normal. We had "cured" our patient of 21-hydroxylase deficiency (but not of hirsutism) merely by reading the chart! We learned a valuable lesson about rechecking laboratory values, and about being careful when recording test results.

Treatment

Low-dose glucocorticoid replacement (with prednisone or prednisolone) is considered the therapy of choice in treating attenuated 21-hydroxylase deficiency.^{1,3,5} This seems somewhat counterintuitive, since baseline cortisol levels tend to be normal.^{4,6} In fact, these

normal cortisol levels are achieved by activating the entire adrenal steroidogenesis system, increasing ACTH, and driving the adrenal glands harder. Cortisol is normal, but the cost is elevated levels of other adrenal hormones. Supplying glucocorticoid by mouth provides negative feedback to ACTH, allowing more normal adrenal functioning. However, in most studies, prednisone-treated women with this disorder report improvement in fertility, acne, and oligomenorrhea, but not in hirsutism.^{4,5} This suggests that the hirsutism may not be caused by the enzyme deficiency, or that another factor (such as obesity or excess androgen sensitivity) may be implicated in the clinical expression of the deficiency.

Kuttann and colleagues⁴ measured skin 5-reductase activity in patients with attenuated 21-hydroxylase deficiency to assess sensitivity to androgens. They found generally normal levels and suggested that androgen overproduction rather than increased sensitivity accounted

for the hirsutism in their patients. Nevertheless, differences in sensitivities to androgens may account for different degrees of hirsutism in women with this disorder, and also for the sensitivity, or lack thereof, to glucocorticoid treatment.

Several authors recommend anti-androgens, such as spironolactone, in the treatment of hirsutism.^{1,4} By inhibiting the action of androgens on their receptors, these agents can help diminish excessive hair growth. Even in clear-cut cases of attenuated 21-hydroxylase deficiency, anti-androgens can help but it is especially indicated in patients such as ours who have idiopathic hirsutism and do not need prednisone. Because spironolactone is also an anti-hypertensive, it seemed a good drug to try in our patient, and we have started her on it. We are also emphasizing the importance of weight reduction in helping her with the hirsutism and with hypertension. □

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The Content of One Doctor's Practice

Relevance of the Biopsychosocial Model

William H. Howell, M.D.

Doctors would study and publish the content of their own practices if they thought the data would prove pertinent to the issues of their own time. In 1972 John Burnum described his practice in internal medicine¹ with particular reference to the proper role and training of the internist regarding the dual functions of specialist and primary care physician. I offer the present description of a single practice in internal medicine because it has helped me understand the psychosocial work of doctoring and the implications that such work has for me and for the training of generalists. The perspective I take here has evolved through practice and study; it might best be explained by some personal background and intellectual history.

In 1977, my first year in practice, I came across Castelnovo-Tedesco's *The Twenty Minute Hour*, which taught me the value and technique of a systematic long interview.^{2,3} From the start I found that eliciting a comprehensive personal biography and social history could break the impasse that occurred when physical symptoms refused to yield to biomedical explanations. The stories that unfolded and the emotional release the patients experienced were gratifying and appeared to help me clinically. An example will illustrate:

Mrs. C., age 36, complained of an intermittent "tightness" in her chest and throat. She also complained of restlessness, early morning awakening, loss of energy, and loss of pleasure from her life. The medical history and physical exam, coupled with appropriate laboratory studies convinced me that she had no heart disease or other significant organic

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problem. I suggested that she was depressed, but she was reluctant to accept my diagnosis. She did agree to return for a long interview. The story that unfolded showed that she was a compulsive high achiever, the daughter of alcoholic parents. She was in the midst of a marital and financial crisis precipitated by irrespon-

sible borrowing and spending on the part of her husband. The feelings that accompanied her story were intense, with an outpouring of anger and tears. The diagnosis became more certain to me and obvious to her. She accepted a prescription for a tricyclic anti-depressant and sought marriage counseling. She improved. Our satisfactory therapeutic alliance has continued.

Through experiences like this, I have learned to make a comprehensive personal and social history and a deeper understanding of the patient a valued part of my practice. I need to explain two concepts, which I came across by reading, that were crucial to my clearer understanding of the psychosocial work of doctoring.

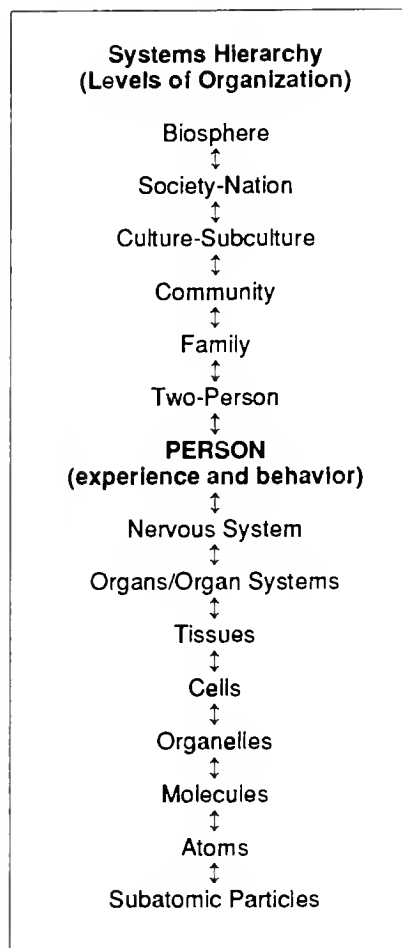
The Balint Agreement

The first concept was the diagnostic agreement between doctor and patient described by Michael Balint:⁴

"[Some people], for some reason or other, find it difficult to cope with the problems of their lives [and] resort to becoming ill. If the doctor has the opportunity of seeing them in the first phases of their becoming ill, i.e., before they settle down to a definite "organized" illness, he may observe that these patients, so to speak, offer or propose various illnesses, and that they have to go on

From the Norwood Clinic and Carraway Methodist Medical Center, Birmingham, AL 35283.

Figure 1: The Hierarchy of the Biosychosocial Model¹⁸



offering new illnesses until between doctor and patient an agreement can be reached, resulting in the acceptance by both of them on one of the illnesses as justified."

I have come to use the term "Balint agreement" to mean a mutually comfortable "medical" diagnosis that the doctor and patient agree on in lieu of a psychiatric diagnosis. For example, panic disorder is sometimes called "mitral valve prolapse" or depression is called "chronic fatigue syndrome." The doctor may be satisfied with the "medical" term used to describe the patient's condition and therefore unaware of entering into a Balint agreement.

Closely related to the Balint agreement is the concept of level of diagnosis.⁵ Even an accurate diagnosis may serve as a Balint agreement that protects against

exploration of a deeper psychological problem. For example, "irritable bowel syndrome" may be an appropriate diagnosis on one level, but act as a Balint agreement protecting against a diagnosis of depression at a deeper level.

Balint agreements are medically and culturally sanctioned. They permit the sick role to people in distress. For example, in France, until recently, patients with symptoms of insomnia or nervousness or loss of energy were often given a diagnosis of "crise de foie" (liver crisis) even though there is no such disease. Even today French physicians may attribute such symptoms to a "sensitive" liver.⁶ Balint agreements may hinder recognition and care for treatable problems such as anxiety and depression, or Balint agreements may be innocent. I cannot completely avoid them as when I list a symptom on the charge ticket in lieu of a psychiatric diagnosis to avoid a cut in my fee. This represents a Balint agreement with the insurance company.

The Balint agreement is widespread and might explain some inconsistencies in epidemiologic data. For example, the National Ambulatory Medical Care Survey⁷ reported in 1981 that 3.3% of outpa-

tient visits to internists were due to nervous and mental problems. But somatization is reported⁸ to account for 25% to 75% of visits in primary care, and the prevalence of mental illness in the general population is reported at 13%,⁹ and many of these patients present to primary care physicians with physical complaints.^{10,11} I think the main reason for the low figure of 3.3% in the National Ambulatory Medical Survey is the widespread medicalization of social and psychiatric problems via the Balint agreement. The following example will illustrate how important Balint agreements may be:

A 73-year-old widow first saw another physician because of nocturnal chest "tightness" and "smothering" and a feeling of impending doom. An exercise electrocardiogram was normal. Coronary angiography revealed 80% stenosis of the right coronary artery. Anti-anginal medication did not stop her nocturnal spells. Her chest pain was interpreted as angina at rest and she received a coronary artery bypass graft. Two weeks after discharge she was re-admitted with the same symptoms; her ECG and cardiac enzyme levels were normal. A pulmonary consultant found mild obstructive disease by

Table 1. Definitions of Psychosocial Variables

Somatization	"...expression of emotional discomfort and psychosocial stress in the physical language of bodily symptoms." ¹⁹ Scored positive if somatization (or anxiety or depression) was the principal reason for seeking medical care.
Balint agreement	A mutually comfortable diagnosis on which doctor and patient agree in lieu of a psychiatric diagnosis. ⁴ Balint agreements give an estimate of the number of psychosocial problems dealt with in biomedical terms.
Therapeutic listening	Listening empathetically while the patient confides personal information, ventilates strong feeling, weeps openly, or talks about matters that deeply disturb him.
Long interview	A systematic personal history including a description of the patient's background, life history, work, marriage, family, and time usage.
Major psychosocial factors or somatization	Scored positive if noted at any time that patient has been seen in my practice. This is the most inclusive evidence of the psychosocial content, diagnostically, of the practice.

Table 2. A Single Day of Practice

	Classification* (Key adjacent)				
	S	BA	TL	LI	MPF
Hospital: Morning Rounds					
1. Mr. T, age 62. Congestive heart failure. Talks about domestic problems of recent weeks. No diuretics or antihypertensives for one year.	-	-	+	-	+
2. Mr. F, age 32. Pharyngitis; fever, resolving.	-	-	-	-	-
3. Mrs W, age 74. Parkinson's disease, dementia. Admitted she sings or yells all night.	-	-	-	-	+
Clinic					
4. Mrs. G, age 54. Annual exam. Very friendly. Dressed up; meets criteria for somatization disorder. Many complaints, no findings; several Balint agreements operating. Confiding personal problems stabilized our relationship.	+	+	+	+	+
5. Mrs. L, age 70. Musculoskeletal hip pain; hypertension, heart failure.	-	-	-	-	-
6. Mrs. K, age 54. Annual exam; feels good. Usually brings long list of small complaints; anxiety, palpitations. Often discusses important personal matters.	-	-	+	-	+
7. Mrs. E, age 74. "Raw" mouth, normal exam. One of four patients in practice meeting full criteria for somatization disorder. Friction with daughter.	+	+	+	+	+
8. Mrs. P, age 64. Dysesthesia of right arm; recent stroke. History of myocardial infarction and bleeding ulcer.	-	-	-	-	-
9. Mrs. R, age 94. Follow-up drug-induced gastritis.	-	-	-	-	-
10. Mrs. L, age 46. Vaginal candidiasis; Type II diabetes. Has attempted suicide since I have been her doctor.	-	-	+	-	+
11. Mrs. L, 70. Prescription for sleeping pills. Emphysema; depression; peptic ulcer.	+	-	-	-	+
12. Mrs. T, age 74. Metatarsalgia. Comes for headaches, depression, to vent feelings.	-	-	+	-	+
13. Mr. R, age 19. Chest pain follow-up; negative evaluation. He is "depressed."	+	-	+	-	+
14. Mrs. S, age 34. Follow-up flank pain and indigestion; on cimetidine for "acid stomach." Evaluation negative. Getting a divorce, doesn't want to discuss. History of emotional and functional problems.	+	+	-	-	+
15. Mr. C, age 18. Father brings in for "check" before final exams. Seizure disorder, does poorly in school. No recent seizures; has felt well.	+	-	-	-	-
16. Mrs. H, age 54. Follow-up congestive heart failure and thrombophlebitis.	-	-	-	-	-
17. Mrs. L, age 74. Low back pain after a fall; exam, x-rays negative. Diabetes, paroxysmal atrial fibrillation, depression.	-	-	-	-	+
18. Mr. C, age 49. Father of patient #15. Annual exam. Has diabetes, hypertension depression, migraine, anxiety attacks.	-	-	+	-	+
19. Mr. N, age 55. Chest pain due to costochondritis. Coronary artery disease, diabetes, benzodiazepine addiction. Sees me for his heart, another doctor for benzodiazepines.	-	-	-	-	+
20. Mrs. B, age 56. Worked in for "sticking" pain in left breast; exam and mammogram normal. Says her daughter has "lupus and one of her breasts turned bloodshot." Says "lupus is a form of cancer." She has "bad nerves."	+	-	-	-	+
Hospital: Evening Rounds					
21. Mr. M, age 83. Referred, mass on chest x-ray. Gradually progressing aphasia, right hemiparesis.	-	-	-	-	-
22. Mr. C, age 66. Admit for cerebral angiogram one month after small left cerebral infarction.	-	-	-	-	-

***Key:** S (+/-) This contact is/is not due to somatization.

B (+/-) A Balint agreement is/is not present.

TL (+/-) Therapeutic listening has/has not ever taken place.

LI (+/-) Patient has/has not ever had a long interview.

MPF (+/-) Major psychosocial factors or somatization have/have not been noted at any time.

spirometry and prescribed a bronchodilator. The nocturnal attacks returned after discharge. I saw her for the first time at this point.

I learned that two youths had robbed her in the parking lot of her apartment building just before the nocturnal attacks had begun. Her family said she didn't have these attacks if someone stayed with her at night. Prescribing an anti-anxiety agent helped her, but relocating to live with a relative ended the illness.

The Biopsychosocial Model

The second concept that has been helpful to me is the biopsychosocial model of George Engel.¹² Engel proposes that the conceptual framework used by Medicine to explain disease and illness must include a hierarchy of natural systems (Figure 1, page 405) in order to be adequately broad and inclusive. Engel bridged the gap between the art and science of medicine by pointing out that the scientific domain of medicine should be "biopsychosocial" rather than narrowly "biomedical." Engel's ideas reinforce the scientific validity of a person-centered approach in medical practice.¹³ As a practitioner I have found the biopsychosocial approach most helpful with the most difficult and frustrating patients, the somatizers.

Although I have been stimulated and challenged by the concepts of Balint and Engel and have found them broadly applicable, they are not in general use in medical care. That is why I wanted to tabulate the way I applied these ideas in my own practice and I offer my observations as pertinent to the practice of medicine in general.

The Practice Under Study

My sample consists of the patients I saw from July 11, 1988, through August 10, 1988. In addition, I give a detailed account of all the patients seen on a single day outside the sample period. I am a board-certified internist at the Norwood Clinic, a 97-man multispecialty group practice in Birmingham, Alabama. My hospital practice is in the adjacent Carraway Methodist Medical Center, a 419-bed teaching hospital. I have been in practice at this location since July 1977.

Data Collection

During the study period a daily photocopy of each office outpatient progress note and the computer list of my hospital patients was reviewed and scored according to age, diagnosis, and several psychosocial variables (Table 1, page 405). Of these variables, only age is completely externally verifiable. The diagnosis is sometimes externally verifiable but it is often only a clinical impression. The psychosocial scores predominantly represent my impressions and are not externally verifiable. Documentation that a long interview occurred can

be found in the medical record as can that for some major psychosocial problems such as a suicide attempt. Recognizing that no two physicians diagnose or categorize patients in exactly the same way, I have included the description of a single day of practice with my psychosocial classification for each patient (Table 2, opposite) in hopes that this will help the reader judge the plausibility of my data.

Results

During the 31-day sample period I had 441 contacts with 254 patients. Table 3 shows the ten most common principal diagnoses in these patients. These ten account for more than half of all principal diagnoses given.

In 84 of the 254 patients (33%), somatization was the primary reason for their contact with me during the study (Table 4, next page). Twenty-five (10%) of the 254 patients were judged to have a Balint agreement operating during the 31-day study period. One hundred seventy-six of the 254 patients (69%) were judged to have had a major psychosocial element or to have had somatization as the primary reason for seeing me at some time during our relationship, and therapeutic listening had occurred at some

Table 3. Ten Most Common Principal Diagnoses in Study Patients

Diagnosis	Number	Percent
Hypertension	31	12.2%
Depression	20	7.9%
Low back pain; Sciatica	17	6.7%
Anxiety; Panic Disorder	16	6.3%
Peptic Ulcer; Gastritis; Esophagitis	12	4.7%
Congestive Heart Failure; Arrhythmia	12	4.7%
Diabetes Mellitus	10	3.9%
Osteoarthritis	10	3.9%
Angina; Ischemic Heart Disease	7	2.8%
Irritable Bowel Syndrome	7	2.8%

time with 98 (39%). A formal long interview had been carried out at some time with 17 (7%) of the 254 patients.

Discussion

My practice seems representative of published data from other primary care settings. The 33% rate of somatization is comparable to that reported by others.⁸ The rates of diagnosed depression and anxiety (7.9% and 6.3% respectively) are close to those found in other primary care settings.^{14,15} Finding that 69% of my patients had a major psychosocial contribution to their illness at some time in our relationship confirms that psychosocial problems commonly stimulate patients to seek medical care and suggests that this is normal behavior, not a manifestation of mental illness.

The 10% prevalence of Balint agreements seems to me significant since I try to avoid Balint agreements by using a biopsychosocial approach from the beginning. Patients with somatoform psychiatric disorders¹⁶ (somatization disorder, conversion disorder, hypochondriasis, somatoform pain disorder) usually will not accept such diagnostic labels, and so I occasionally have to choose between entering into a Balint agreement

and losing the patient. Patients with milder forms of somatization and those who are anxious or depressed will often accept their diagnosis. Nevertheless, uncertainty, haste, lack of rapport, and previously applied diagnostic labels all contribute to the formation of Balint agreements.

I try to keep Balint agreements from leading me into unnecessary intervention or from hindering the treatment of psychiatric disorders. The best way to do this is by therapeutic listening. Nothing else does so much to reduce the intense de-

“Therapeutic listening
builds the
doctor-patient
relationship and gives
both doctor and
patient a unique
personal perspective
on the illness.”

mands for diagnosis and therapy that all doctors have experienced from severely somatizing patients. The value of therapeutic listening goes far beyond its use with somatization and Balint agreements.

Therapeutic listening builds the doctor-patient relationship and gives both doctor and patient a unique personal perspective on the illness. Listening skills help doctor and patient to make difficult collaborative decisions, especially with chronically ill patients and angry patients, as well as with anxious, depressed, and somatizing patients.

In the constraints of actual practice, I find that I have done a long interview with 7% of my patients and have listened therapeutically to 39% of my patients at sometime during the course of my relationship with them. I do most of my therapeutic listening in the context of history and physical, of annual exams and routine visits, but I continue to value the long interview. The following example illustrates a chronic medical patient who seemed to be helped by a long interview.

Mrs. W., age 64, had near end-stage emphysema. She was thin, energetic, and witty. She smoked 20 cigarettes a day and projected an air of bitterness and defiance. She admitted to depression and I gave her a tricyclic anti-depressant, but she did not improve. In a long interview she told the story of her childhood poverty, of an unfaithful husband, and of a job that was satisfying until she had to give it up due to severe emphysema. She

Table 4. Psychosocial Classification of Patients Seen During a 31-day Period

	All	Hospital	Clinic	Male	Female
Seen for somatization symptoms during 31-day study period	84/254 (33%)	8/27 (30%)	76/227 (33%)	29/97 (30%)	55/157 (35%)
Balint agreement during 31-day study period	25/254 (10%)	2/27 (7%)	23/227 (10%)	7/97 (7%)	18/157 (11%)
Therapeutic listening, ever*	98/254 (39%)	6/27 (2%)	92/227 (41%)	30/97 (31%)	68/157 (43%)
Long interview, ever*	17/254 (7%)	2/27 (7%)	15/227 (7%)	5/97 (5%)	12/157 (8%)
Major psychosocial factor or somatization, ever*	176/254 (69%)	13/27 (48%)	163/227 (72%)	61/97 (63%)	115/157 (73%)

*At any time during the author's relationship with the patient.

wept heavily while describing her painful marriage, her lost health, and the career she had to drop due to hospitalizations. Over the next few weeks she seemed to accept her losses and regained an ability to enjoy life. She stopped smoking and switched to nicotine gum.

Another example illustrates the use of therapeutic listening with a difficult somatizing patient:

A plump, middle-aged, bleached blonde crashed into my practice, forced by an insurance change. She didn't really want to see me. She just wanted a referral to a neurosurgeon for intraspinal injections for back pain, and she demanded narcotic prescriptions by telephone. She was angry when I attempted to limit narcotics to a pattern that I considered judicious and appropriate. She called almost daily with demands and complaints. Her symptoms and disability were out of proportion to the moderate degenerative disease in her spine, and she had lots of other symptoms.

In a long interview she related how she was orphaned at the age of three. She never had a stable childhood home, but lived with various older siblings. The

only attention she ever got was when she was sick. At age 14 she tried to escape by marrying a man who was a drinker and abusive, and she stayed with him for 20 years before divorcing him. She had remarried a policeman who was almost always away from home. There was considerable turmoil involving the lives of her children by both marriages.

Over an 18-month period she developed a trust in me and stopped being demanding. During her visits I examined her carefully for her physical complaints and listened to her problems in living and her conceptions about her illness. She herself began to note the connection between her problems in living and her illness. Now she no longer visits the neurosurgeon, and her narcotic consumption has stabilized at less than half of its previous level. She values her relationship with me and feels she is "doing better" than she has in many years.

Using the doctor-patient relationship to bring about this kind of gradual improvement in a difficult somatizing patient has been described in more detail by others.¹⁷ For me, learning to listen has been a struggle against the time and eco-

nomie constraints of practice, but clearly the psychosocial aspects of practice are a major part of my work. I can schedule a long interview when time is available. Other listening tasks usually occur in 15- or 30-minute office visits. Overcoming the time and economic constraints was no more difficult than overcoming my fear of opening up to a deeper and more comprehensive type of care. What if the patient should be offended? What if I should miss a diagnosis? I know I will miss some diagnoses; can I open myself up to that risk? Will I just be used up getting involved in messy lives that I can do nothing about? In fact, since I have taken that path, I am sure that my work is more effective and more satisfying for me and for my patients. The biomedical superficiality of general medicine (when compared to a medical subspecialty) has been offset by the personal, moral, and intellectual breadth and depth that I have found. I have been able to engage the major issues and to relate to the patient and to the broader health care system at a very meaningful and significant level. □

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REMEMBER

1975?

JANUARY 1 H.R. HALDEMANN, JOHN C. MITCHELL AND JOHN D. EHRLICHMAN, FORMER TOP AIDES OF PRESIDENT RICHARD NIXON, ARE CONVICTED OF CONSPIRACY TO OBSTRUCT JUSTICE IN THE WATERGATE CASE. **FEBRUARY 11** MARGARET THATCHER IS ELECTED LEADER OF THE CONSERVATIVE PARTY, BECOMING THE FIRST WOMAN TO HEAD A BRITISH POLITICAL PARTY. **APRIL 30** THE SOUTH VIETNAMESE GOVERNMENT SURRENDERS TO THE COMMUNISTS, ENDING THE WAR IN VIETNAM. ♦ **SEPTEMBER 29** THE MALPRACTICE SITUATION IN NORTH CAROLINA REACHES A CRISIS AFTER THE LAST COMMERCIAL INSURANCE COMPANY ANNOUNCES IT WILL NO LONGER PROVIDE MALPRACTICE COVERAGE IN THE STATE. ♦ **OCTOBER 1** IN MANILA, MUHAMMED ALI DEFEATS JOE FRAZIER IN THE FIFTEENTH ROUND TO RETAIN THE WORLD HEAVY-WEIGHT BOXING TITLE. ♦ **OCTOBER 23** NORTH CAROLINA PHYSICIANS CREATE A MUTUAL INSURANCE COMPANY TO ASSURE A STABLE, FAIR PROFESSIONAL LIABILITY MARKET. ♦ THE YEAR'S TOP FILMS INCLUDE *JAWS*, *ONE FLEW OVER THE CUCKOO'S NEST*, AND *NASHVILLE*.

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Health Watch

VOLUME 53 / NUMBER 8 / AUGUST 1992

Health Issues of the Young

YOUTH AND TOBACCO: ADDICTION AND DEATH Adam O. Goldstein, MD

Myth

Cocaine and marijuana are the most frequent drugs used by youth in North Carolina.

Fact

One out of every four North Carolina adolescents uses cigarettes or smokeless tobacco on a regular basis compared to one out of ten who uses marijuana, cocaine or other drugs.

Myth

Tobacco companies do not want children to smoke cigarettes or use smokeless tobacco.

Fact

The tobacco industry spends over \$3.5 billion yearly promoting their tobacco products, much of which is directed at youths.

Dr. Goldstein is a clinical instructor and primary care researcher in the Department of Family Medicine at the University of North Carolina School of Medicine in Chapel Hill. He also serves on the North Carolina Medical Society Tobacco Control Task Force.

Myth

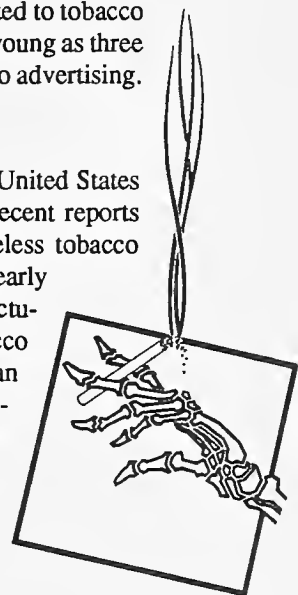
Use of tobacco products is an adult habit and the choice is made after knowing the benefits and risks involved.

Fact

Over 90% of people who become addicted to tobacco do so before the age of 21. Children as young as three years of age are already aware of tobacco advertising.

Overview

While tobacco use among adults in the United States has decreased over the last 25 years, recent reports show that use of cigarettes and smokeless tobacco among adolescents has not decreased nearly as rapidly and in some situations may actually be increasing. In some cities, tobacco use among adolescent girls is greater than among adolescent boys. The use of smokeless tobacco products, including snuff and chewing tobacco, remains a serious health hazard among youths, particularly boys.

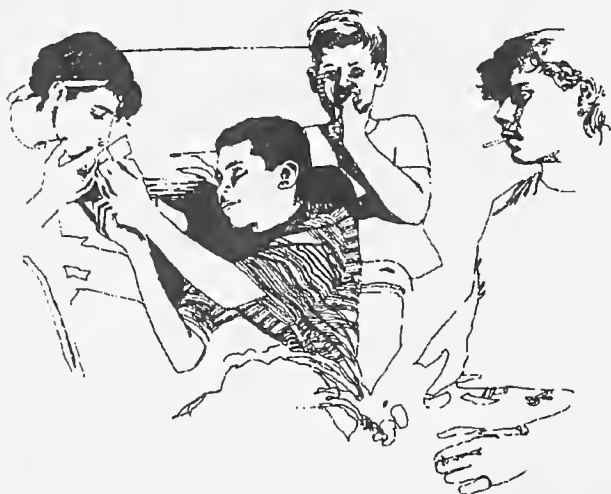


Tobacco products are well known to be the "gateway" drugs to almost all other drugs, including alcohol. Unfortunately, as an experimental agent, tobacco is quite deadly and addicting. Research shows that once an adolescent or adult is addicted to tobacco, smoking cessation for that individual is very difficult and compares to what a heroin addict goes through in attempting to quit using heroin. Over 100,000 North Carolina youths may well have significant tobacco addictions.

Environmental tobacco smoke is also a serious health hazard to our youth. Children who live with parents or other adults who are cigarette smokers have many more episodes of upper respiratory infections, inner ear infections, asthma and allergies. Exposure to environmental tobacco smoke increases children's risk of developing lung cancer sometime in their lifetime by at least 30 percent. The best way to eliminate a child's exposure to environmental tobacco smoke is for the parents and other family members and friends who smoke to stop smoking.

Why do adolescents start smoking?

There are many reasons why youths begin to smoke cigarettes, but the two most important factors are parental and other family smoking and the marketing of tobacco products to youths by the tobacco industry. "Peer pressure" is simply a phrase that describes what happens when young people use tobacco products to influence others to use the same products. However, peer pressure itself is often initiated and sustained by the tobacco industry. For instance, RJR sponsors the Winston Road Races and Phillip Morris sponsors the Virginia Slims Tennis Tournaments. These events and thousands of other promotions, sports sponsorships and concerts (Marlboro County Music Festival), attract thousands of youths to lifestyles that are considered healthy, exciting, good look-



ing and financially rewarding. It is no coincidence that these same events are associated with tobacco products and imply that "smoking" or a "pinch of snuff" will lead to happiness and success rather than addiction, disease and often death.

Recently, the RJ Reynolds' use of the cartoon character "Old Joe" has proven to be very successful in addicting many North Carolina youths to use Camel cigarettes. Research reported in the *Journal of the American Medical Association* showed that Old Joe was as well recognized by 6-year-old students as was a picture of Mickey Mouse, and that RJR was as effective as Walt Disney in reaching such young children. The use of a cartoon figure to promote a deadly product, the multiple free gifts such as "Camel Cash," caps and sunglasses, beach towels and coolers, all serve to create the "peer pressure" that helps entice young people to experiment with, regularly use and eventually become addicted to tobacco products. Candy cigarettes are even used to help get kids "hooked" while they are too young to know any different.

It is also true that if a parent or an older family member is a regular tobacco user, children are more likely to use tobacco products at earlier ages. Yet few parents want their children to start smoking cigarettes or become addicted to smokeless tobacco. Such parents can become appropriate and good role models by deciding to quit using tobacco products themselves.

How can I prevent my children from using tobacco products?

- Don't use tobacco products yourself.
- Talk to your children about the long term and short term consequences of tobacco use, letting them know that they risk getting lung cancer, heart attacks, emphysema, ulcers and many more medical illnesses, but also emphasizing the smelly clothes, hair, yellow teeth and nails.
- Remind them that smoking is a very silly habit as well as an addictive one and that 90% of teenagers would prefer to go out with someone who is a non-smoker.
- Explain to youth how the tobacco industry is using them to market their products and how such exploitation leads to more money and profits for the industry while it leads to disease and death for the adolescent.
- When you go by billboards or other advertisements for tobacco products, direct their attention to the warning label and talk about how small that warning is in relation to the overall theme of the advertisement. Does the advertisement accurately reflect the true nature of tobacco?
- Subscribe to magazines that do not accept tobacco advertisements.

- Ask your local school principal and teachers about their tobacco education curricula in the school systems.
- Volunteer to help coordinate a pro-health, anti-tobacco advertising campaign for school children, and put the winning advertisements up on billboards and other media throughout your cities.
- Protest tobacco companies' sponsorship of sporting and cultural events and show your children that they can enjoy entertainment that is healthy and non-drug addicting.
- Sponsor your own smoke-free youth baseball, softball or soccer club.
- Write to your local city council, chamber of commerce, county commissioners and state legislators demanding that local ordinances be passed prohibiting free sampling of tobacco products and banning the use of vending machines, means whereby many adolescents obtain their tobacco products. Insist that local law enforcement agencies vigorously apply and enforce such statutes.

"Nicotine is as addictive as heroin."

—1988 Surgeon General's Report

- Write letters to local and national pharmacies and grocery stores, including convenience outlets, protesting their active participation in promoting death and disease to your children. Tell grocery stores to remove tobacco promotions from grocery carts where your children often sit.
- If you are a non-smoker, encourage and be supportive of smokers attempting to quit.
- Talk to middle and high school coaches to make sure they disapprove of cigarette and smokeless tobacco use among their athletes and students.

My children are experimenting with tobacco products; how can I get them to quit?

If your children are already using or thinking of using tobacco products, they are at very high risk for a lifelong addiction. Sit down and talk with them about tobacco products and why they may be using them. Make sure that they know the health consequences and at the same time emphasize that it is their decision.

If your children are regular tobacco users and want to quit smoking, help direct them to one of the many resources that can assist them in smoking cessation. The American Cancer Society and the American Lung Association offer smoking cessation classes as well as self-help smoking cessation brochures. To locate the nearest class or to receive information, contact your local American Cancer Society or American Lung Association branch.

North Carolina is one of handful of states that has received large National Cancer Institute grants to implement a broad array of smoking cessation activities. Called ASSIST, American Stop Smoking Intervention Study for Cancer Prevention, the North Carolina ASSIST project will reach into many communities throughout the State. For a list of programs and questions about how you can become involved in North Carolina ASSIST activities, please call Project ASSIST at (919) 733-1881.

The North Carolina Medical Society has formed a state-wide task force on tobacco control in North Carolina. One of the primary goals of this task force is to help make North Carolina smoke free by the year 2000. Such a goal will not be reached unless we prevent our children from becoming addicted to tobacco products. As a state with traditionally very strong ties economically to tobacco income we must assist individual tobacco farmers and those who rely on tobacco income to find alternative jobs, crops and careers. However, we must not allow the number one cause of preventable death, disease and murder worldwide, in the United States, and in North Carolina to take our youths every day in the name of corporate profits.

Summary

Tobacco use by youth is a serious problem that can be handled by the combined attention of parents, youth advocates, health professional and youths themselves. Tobacco related addictions kill over 2,000,000 people worldwide every year and over 8,000 people in North Carolina. The best way to end such killings is to focus on prevention. Adolescents themselves can become leading advocates for a smokefree society and a healthier North Carolina for all of us. □

1992

September *Health Issues of the Young*

October, November, December *Prescription Drug Use*



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Human Immunodeficiency Virus Infection at New Hanover Regional Medical Center

John K. Keku, M.D., M.P.H., Peter C. Ungaro, M.D., and Jane E. Ranney, Ph.D.

In recent years a substantial number of patients with human immunodeficiency virus (HIV) infection have been admitted to hospitals in North Carolina. Although the HIV epidemic initially seemed to be confined to large urban areas, increasing numbers of cases have been identified in areas of lower population density, and now community hospitals in many parts of the state are encountering considerable case loads.¹ There has been some controversy about the adequacy of care and the role of various physicians in providing this care.² The function of resident physicians in the management of these patients has also been of concern.³ The New Hanover Regional Medical Center (NHRMC) experience provides interesting information about the characteristics of hospitalized HIV-infected patients and the response of local physicians to meeting the needs of these patients.

The hospital is a 550-bed teaching hospital with residency training programs in obstetrics/gynecology, surgery, and

From the New Hanover Regional Medical Center and the Coastal AHEC, Wilmington, NC, and the Department of Medicine, School of Medicine, University of North Carolina at Chapel Hill.

Table 1. Risk Behavior* by Race

Risk Behavior	African American	White	Hispanic
Homosexual	19	31	2
IV Drug User	41	8	0
Heterosexual	24	8	0
Transfusion	2	0	0

*A single patient may have more than one risky behavior.

internal medicine. It is located in a county with a population of 125,000, and it serves as a referral institution for the adjoining four counties. HIV-infected patients are seen as inpatients and in both general and infectious diseases clinics.

Methods and Results

We reviewed hospital charts of the 128 patients with HIV infection who were admitted from 1985 through 1991. The mean age of the patients at time of HIV diagnosis was 33.7 years with a range of 13 to 71. African-Americans accounted for 81 cases (63%), whites 45 (35%), and Hispanics 2 (2%). Ninety-five (74%) were males. Seventy (55%) met the diagnostic criteria for the acquired immunodeficiency syndrome (AIDS), 41 (32%) had generalized lymphadenopathy, and 17

(13%) were identified at an even earlier stage in their course.

Table 1 shows that the patients tended to be either white homosexuals or African-American intravenous drug users. Historical information indicated that 65 patients had acquired the disease in North Carolina (61 within the five-county area served by NHRMC), while 67 acquired their disease at a distant site and came to this area after being infected. Forty-three (64%) of those infected outside of the region had AIDS rather than earlier infection, while only 27 (44%) of those acquiring infection in the region had AIDS at the time of initial admission.

The number of new cases (first admissions) increased with each succeeding year until 1989 and then leveled off, as can be seen in Table 2. From 1982 to June 1, 1992, these 128 patients had 353 NHRMC admissions for a total of 4,421

Table 2. New cases of HIV Disease Admitted to NHRMC Each Year

Year	Number
Before 1985	2
1985	3
1986	6
1987	17
1988	19
1989	29
1990	26
1991	26

hospital days, not including holding and observation stays or ambulatory surgery. The multiple opportunistic infectious and AIDS-associated malignancies encountered in this patient population are shown in Table 3. Fifty-one (40%) of these 128 patients were known to have died by the end of May 1992.

During the study period, the percentage of patients for whom internal medicine house officers served as principal physicians during hospitalization increased from 53% to 81% (Table 4). As principal physicians, these house officers were responsible for all aspects of the patients' care under the supervision of a faculty attending physician. Although consultant specialists and others often provided services, the burden of responsibility fell on the principal physician, who was identified by the patient and the family as the doctor primarily responsible for all aspects of care, including psychosocial support. When house officers were not involved in a patient's care, the admitting attending physician was designated the principal physician.

When first admitted, 51 patients (40%) had Medicaid or Medicare insurance coverage, and 25 (20%) had private insurance, leaving 52 (41%) with no third-party coverage. During the study period 25 private practitioners provided 157 consultations. All four infectious disease specialists and five pulmonologists participated. Until 1988 there was an infectious disease specialist at NHRMC with a special interest in HIV infection. He

Table 3. Infections and Malignancies* in HIV Patients

Type	Number of cases
Candidiasis	79
Oral	71
Esophageal	5
Genital	10
Cytomegalovirus (CMV)	44
Pneumocystis	43
Hepatitis B	36
Herpes Simplex	32
Tuberculosis	25
Local	20
Disseminated	5
Syphilis	21
Toxoplasmosis	13
Kaposi's Sarcoma	10
Gonorrhea	10
Herpes Zoster	8
Cryptococcus	8
Lymphoma	8

*A single patient may have more than one diagnosis

served as principal physician in 27% of cases and consulted on 66% of the others. The two infectious disease specialists who have been here since 1989 served as principal physicians for 9% of the hospitalized patients and as consultants on 45% of the other HIV patients.

Discussion

The number of HIV-infected patients admitted to the hospital has challenged the medical community. Many practitioners have been involved in the care of these patients, both as principal physicians and as consultants. These practitioners have had to become familiar with a new disease process—one with multiple complications, many of which were either in-

countered or unknown in this region prior to 1987. The number of hospitalizations and the number of days in the hospital indicate the extent of health care resources devoted to dealing with these patients. This is in accordance with the experience of others.⁴

Along with the requirement for new medical knowledge and resources has come the necessity for dealing with the psychosocial implications of the disease. The large percentage of patients who have died indicates the magnitude of this problem as others have reported.⁵ It is a severe emotional strain to deal with young patients who have an irreparable disease process that leads to their death.

In 1987 two of our infectious disease specialists were influenced by these developments. One was greatly interested in the disease and enthusiastic about working with patients and educating the public about the disease's implications. He was willing to function as the principal physician for many of these patients and to allow others to serve as consultants. He became known as the "AIDS doctor," and a gap in care was experienced when he left the community. The other infectious disease specialist present in the community in 1987 gave up his subspecialty practice and became a general internist.

The HIV epidemic has altered the practices of infectious disease specialists

Table 4. Principal Physicians of HIV Patients

Year	House Staff	Infectious Disease Specialist	Other Attending Physician
1987	9	5	3
1988	13	2	4
1989	21	4	4
1990	17	2	7
1991	21	2	3

and has had considerable impact on the practices of internists and other physicians. This sudden change in the character of practice could not have been anticipated by trainees prior to the epidemic, but certainly can have considerable impact on current residents' career choices. Although medical practices tend to change with time, especially as new concepts are developed and new pathophysiologic processes and treatments are identified, the changes brought on by the spread of HIV infection have been very rapid. When abrupt changes occur, substantial impacts can be expected, including even career changes.

Several factors might affect the willingness of physicians to deal with HIV-infected patients and to sustain a practice that includes such patients. Being identified as an "AIDS doctor" has some important implications. Non-HIV infected patients who are fearful of the disease may not wish to see such a physician because of their fear that the disease might be transmitted to them. There is the emotional strain of looking after a population of dying young patients. Often these patients have limited financial resources, and their ability to reimburse the physician is limited.

Fear of transmission of the disease to the health care provider is also an important concern.⁶ Some physicians may

not approve of the lifestyles of these patients. Homosexuality, drug addiction, and promiscuity make it possible to judge these patients as having contributed to their disease process, and thus to be less deserving of expensive and time-consuming interventions. Many are African-Americans, and racial prejudice could be a factor.

Whatever the special problems that these patients represent, an impressive number of physicians in this region have been willing to shoulder some of the burden. However, involvement as a consultant is more attractive to local physicians than involvement as the principal care giver. The consultant's role can isolate the practitioner from some of the emotional stress involved in care giving, and it seems to make it much less likely that the practitioner will become identified as an "AIDS doctor." In some instances the consultant's role can be used to minimize contact and possibly the danger of being infected. Often the consultant's duties are less time-consuming than those of the principal care giver.

As a result of these tendencies, much of the burden of providing primary care for HIV patients has been left to residents. Training programs can anticipate caring for more of these patients as more individuals become infected and more effective interventions permit them to

live longer. Placing much of the burden of care for these patients on young physicians in training creates problems that need to be considered. Certainly residents need to become familiar with the care of HIV-infected patients and their special medical and psychosocial problems. However, the strain on the doctor needs to be taken into consideration as well. Ideally residency should provide experience with a mixture of patient problems similar to those that the physician will encounter after training. Too much of any one sort of problem may only detract from the necessary diversity of the educational experience. However, while the HIV epidemic may narrow the spectrum of patient problems, just as important from an educational point of view may be the additional psychological stress that these patients cause for a physician at a time of vulnerability. Part of the value in a residency experience involves developing the emotional resources to deal with tragic situations and fatally ill patients. While seeing a limited number may be important in ensuring this development, a large number may be discouraging or even overwhelming. We need to find financial incentives and other inducements that will encourage more established physicians to share with house staff in the care of these challenging patients. □

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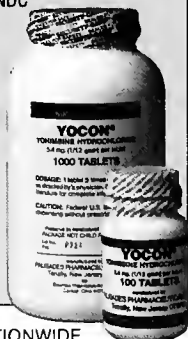
Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

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FIRST-PERSON ESSAY

To Be An Internist

E. Ted Chandler, M.D.

Editor's Note: The following commentary received first prize in an essay contest recently sponsored by the Department of Internal Medicine at the Bowman Gray School of Medicine at Wake Forest University in Winston-Salem.

I was hooked on Internal Medicine upon introduction to my first patient, a fisherman from Southport with congestive heart failure. On Thursday past Sandra came in dressed to kill but in tears; the pain from finger ulcers of scleroderma denied her buttoning her blouse.

In the interval of years between these two patients and from thousands of vignettes, I believe that the work of an internist is to search out the best care for his or her patients, to listen with an empathetic ear and to render that care with compassion.

Disease rarely respects human dignity and beauty, but the empathetic and compassionate internist is peculiarly well equipped to ease the humiliation and degradation of its victims. In this sense the internist's work stands for something larger than itself. It reminds us of our humanity and therefore of the deeper qualities that are essential to our common human existence.

The fisherman's heart responded well to treatment. The best I could do for Sandra was to button her blouse. For me to button was more than a manual act. The disease had robbed Sandra of her dignity, her beauty, her vitality, and her dreams. Her tears are the proof. I rendered care in that act.

As an internist I can order up the most complex of machines in the most efficient of large-scale hospitals, but Sandra's taut skin will be no better perfused. But when she wants to talk I listen. She says she always feels better. I feel worse. Yet I will persist in this one thing, for in this act pain is transferred and what dream remains inside her is salvaged. In this way my work as an internist gives hope, a form of compassion. □

From the Department of Internal Medicine, Bowman Gray School of Medicine, Wake Forest University, Medical Center Boulevard, Winston-Salem, NC 27157-1051.

Detection of Sexually Transmitted Disease at Premarital Examination In a Community Health Clinic

James L. Wofford, M.D.,^{1,2} Karen R. Matthews, M.D.,^{1,2} Joyce W. Beech, P.A.,² Gale L. Harkness, P.A.,² and P. Samuel Pegram, M.D.¹

Screening for sexually transmitted diseases (STDs) before a couple is married was first recommended in the 1930s in an effort to combat increasing incidence rates of syphilis.¹ Premarital screening for STDs was focused primarily on serologic testing for syphilis until the 1980s when studies proved that such screening was not cost-effective.^{2,3} Most states then repealed laws requiring compulsory testing. Premarital screening for HIV infection was even more rapidly shown not to be cost-effective, largely due to results of mandatory screening in the state of Illinois.^{4,5} As a result of experience with these two infections, support for premarital screening for STDs waned.

Most states now require only minimal health screening prior to marriage, and, in many states, contact with a health professional is not required at all.⁶ Where evaluation by a physician is required, wording of the law allows considerable variability in interpretation. Only two states, North Carolina and Florida, require physical examination before medical approval is granted. North Carolina law states that the "usual methods of examination" be used to determine that "no evidence of any venereal disease exists" before a marriage certificate is issued.

Such language permits flexibility in individualizing the patient interview and examination but also places responsibility on the physician in case an STD is found subsequent to the examination. In reality, even in states where physical examination is required by law, physicians actually do little in terms of screening.⁷

Thus, the current approach to premarital screening is conservative. However, the changing epidemiology of STDs argues for more aggressive screening, for several reasons. First, the incidence of STDs, including syphilis, is increasing in the general population.⁸ Second, *Chlamydia trachomatis*, the most commonly diagnosed genital pathogen and a major cause of infertility, was barely recognized at the time that laws requiring premarital testing were repealed.^{1,9,10} Screening of asymptomatic high-risk populations for chlamydial infection is now recommended by public health authorities.^{11,12} Third, there is evidence that physicians do not offer adequate STD screening or patient counseling.¹³ Especially when there is a legal obligation, physicians should not take lightly their written guarantee of freedom from STDs.

We do not know whether premarital applicants represent a group at lower risk

for STDs than adults not applying for marriage. Nor are we sure how the risk for STDs among premarital applicants varies with the clinical setting. In order to better define the value of premarital screening for STDs in an urban public health clinic, we used a standardized questionnaire and physical examination, as well as the testing of sera and cervical or urethral samples to determine the prevalence of syphilis, gonorrhea, and chlamydial infections among premarital applicants.

Methods

Reynolds Health Center is a county-supported, public health facility located in Winston-Salem. A sliding scale fee attracts primarily the medically indigent. All patients who sought the required premarital evaluation from May 15, 1989, to January 15, 1990, were considered eligible for the study. Patients were excluded only if they were less than 18 years old or mentally incompetent. The study was approved by the Clinical Research Practices Committee of the Bowman Gray School of Medicine. Patients registering for a premarital evaluation

From the ¹Department of Internal Medicine, Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, NC 27103, and the ²Reynolds Health Center, Winston-Salem, NC 27103. Abstract published in *Clinical Research* 1990;38(2):717A.

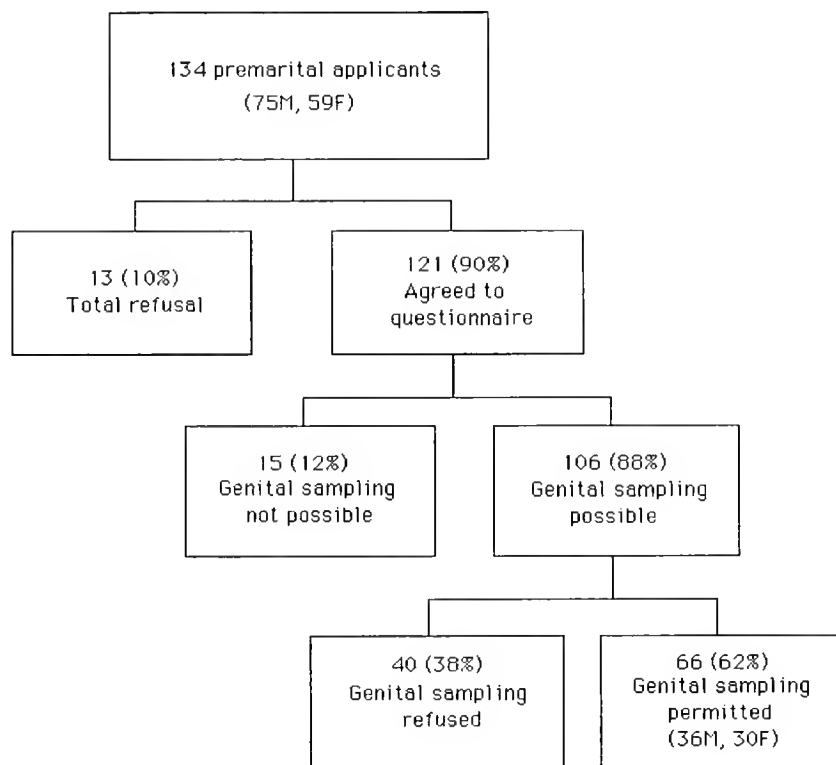


Figure 1: Flow chart of study participation.

were given an appointment two days later with a primary care provider in the general medicine clinic. At the time of registration a blood sample was taken for syphilis serology as required by health center policy, and the results were available at the time of evaluation two days later.

Applicants were seen by one of four health care providers (two physicians, two physician assistants). Informed consent was first obtained and documented. Patients were given the chance to refuse genital sampling and still complete the questionnaire. The health care provider then administered the questionnaire, performed a physical examination, and obtained genital samples according to a standardized protocol. Patients were interviewed by providers of the same gender whenever possible. Demographic data, highest educational level attained, marital history, history of a previous STD or visit to a STD clinic, and presence of genitourinary symptoms were recorded.

All information was recorded and maintained in a confidential manner.

Physical examination included visualization and appropriate palpation of external and internal genitalia. The presence of any abnormality (for example, genital ulcers, inguinal adenopathy, urethral and cervical discharge, genital warts, or pelvic or abdominal tenderness) was noted. Two calcium alginate swabs were used for genital sampling, one for *Neisseria gonorrhoeae* (GC) culture and one for *Chlamydia trachomatis* detection, in that order. With men, the swab was inserted approximately 2 to 4 cm into the urethra and rotated for 3 to 5 seconds before being withdrawn. With women, the swab was placed in the cervical canal and rotated for 15 to 30 seconds before being withdrawn; urethral cultures were not performed.

The GC culture, chlamydia detection, and syphilis serology tests were carried out in the health center laboratory. The GC cultures were directly plated

onto Thayer-Martin agar plates in the clinic and subsequently kept under anaerobic conditions. The plates were read on the first and second days before being declared negative. Abbott Laboratories' Chlamydiazyme ELISA (enzyme-linked immunosorbent assay) for chlamydia antigen was performed by the health center laboratory within two days of collection. Positive rapid plasma reagin (RPR) assays for syphilis were confirmed by repeat testing and compared with records from the STD clinic to determine whether the patient was already known through public health surveillance to be positive.

All laboratory data were considered confidential. When a test was positive for GC, chlamydia, or syphilis, one of the supervising physicians attempted to contact the patient personally by phone and initiate treatment. The positive test result was then forwarded to the public health authorities for contact tracing, as is required by law.

For the purposes of analysis, we grouped together, as subjects in whom genital sampling was not performed, those in whom sampling was impossible and those who refused genital sampling but agreed to answer the questionnaire. The group of patients who did not have genital sampling and the group that did were compared to each other with respect to age, gender, race, educational status, duration of relationship, number of previous children, number of previous marriages, and history of previous STD clinic visits or previous STDs. Chi-square tests were used to assess differences in proportions between the two groups. Student's T-test was used to assess differences in means of continuous variables. In the tested group, the prevalence and 95% confidence intervals (CI) of chlamydial infection were calculated and compared to the prevalence of positive chlamydia antigen tests among attenders of the general medicine clinic who were not being seen for premarital examination, and among attenders of pediatric, obstetrical, and gynecologic clinics located in the same health center facility.

Results

One hundred thirty-four consecutive premarital applicants (75 men, 59 women) were seen in our clinic from May 15, 1989, to January 1, 1990, (Figure 1, at left). Ten percent (13/134) refused to participate in any aspect of the study. Of the remaining 121 patients, genital cultures were not possible in 12% (15/121) for the following reasons: six patients had a surgically absent cervix or were pregnant; one woman with active herpes lesions could not tolerate a speculum examination; laboratory materials for genital sampling were not available for eight patients. Of the 106 remaining patients, 40 (38%) refused genital sampling.

Characteristics of the 66 patients in whom genital sampling was performed and the 55 in whom sampling was not performed are compared in Table 1. There were no significant racial differences between the two groups (71% black versus 69% black, respectively). Patients who did not have genital sampling were better educated (80% had graduated from high school) than patients who did have sampling (56% high school graduates). Participants in whom sampling was not performed had known their fiancé/fiancée slightly longer than participants in whom sampling was performed (4.5 versus 3.3 years) and were less likely to have been married in the past (29% versus 36%). Overall, 31% of those who provided information (32/102) had a history of a previous STD or STD

clinic visit, but the difference between the two groups was not significant (27% versus 39%).

Three patients had findings suggestive or diagnostic of an STD on physical examination. One woman had active genital herpes lesions. Two men had penile ulcers, the causes of which could not be identified before the patients were lost to follow-up. Three patients had a positive serologic test for syphilis, but all had been previously identified as positive through public health surveillance. There were no positive cultures for gonorrhea.

Eight percent (5/66) (95% CI = 2.5% to 16.8%) of those tested had a positive ELISA for chlamydial antigen. None of these patients (three women, two men) were engaged to one another. Furthermore, none of these patients had symptoms, a past history of a STD clinic visit,

or a previous recognized STD. These results are comparable to the 10.1% positive proportion (215/2,130) of chlamydial tests performed by the same laboratory for other clinics in the community health center. For women attending the general medicine clinic (but not undergoing premarital examination), the gynecology clinic, the pediatric clinic, or the obstetric clinic, 9%, 10%, 22%, and 10%, respectively, of chlamydial tests were positive.

Discussion

Prior to undertaking this study we felt that premarital screening for STDs was not worthwhile, and that the law requiring physical examination should be revised. We thought that, in general, pre-

Table 1. Characteristics of Premarital Applicants by Availability of Genital Samples

	Genital Sampling Performed	Genital Sampling Not Performed*	p**
Number of Subjects	66	55	
Mean Age (Range)	29.6 (18-57)	28.9 (17-67)	.72
Percent Male	57.6 (38/66)	54.5 (30/55)	.88
Percent White	22.7 (15/66)	25.5 (14/55)	.89
Percent Black	71.2 (48/66)	69.1 (38/55)	.81
Percent High School Graduates (n = 98)	55.6 (28/63)	80.0 (28/35)	.001
Percent Previously Married (n = 102)	28.7 (19/66)	36.1 (13/16)	.59
Percent Previous STD or STD Clinic Visit (n = 102)	27.3 (18/66)	38.8 (14/36)	.33
Mean Number of Years Knowing Fiancée (n = 102)	4.5	3.3	.13
Mean Number of Previous Children (n = 102)	1.4	1.3	.81

*Patients for whom genital sampling was not performed included those in whom sampling was impossible as well as those who refused genital sampling but agreed to answer the questionnaire.

**Probability that the two groups are not different from one another.

marital applicants would represent a group at lower risk for STDs than young adults not applying for marriage and that this lower risk would hold true even in clinic settings with a high proportion of indigent applicants. By showing a low prevalence for the STDs studied, we hoped to be able to offer evidence that mandatory screening in our state was an unnecessary expense, both for the premarital applicant and the physician. Our results, however, suggest that there may be benefit to screening all patients (including premarital applicants) for STDs, at least in clinic populations similar to ours.

Despite the small number of patients, the prevalence rate of 8% positive chlamydial ELISAs in tested patients is disturbing. Chlamydial infection, now the most commonly reported sexually transmitted disease, causes as many as 20,000 cases of infertility in the United States each year.¹⁴ Chlamydial infection, which may be asymptomatic in up to 80% of cases, comes to medical attention less frequently than gonorrhea but produces a greater severity of tubal inflammation.¹⁵ Screening of high-risk women at the time of prenatal visits is already recommended in an effort to prevent the serious complications of neonatal chlamydial infection.^{16,17} Screening of sexually active women at premarital examination in order to prevent gynecologic complications seems appropriate as well.

Factors such as young age, single marital status, a new sexual partner within the past three months, number of sex partners, low socioeconomic status, ethnicity, and type of health care facility have been suggested as markers of patients at high risk¹⁷ for chlamydial infection. However, these risk factors have not been replicable from one setting to another and have not demonstrated sufficient predictive value to be used in selective screening. As a result, it is recommended that local prevalence rates of chlamydial infection determine screening practices and that universal screening be used in those settings where the prevalence is high.^{12,17} Some authorities have suggested that screening becomes justifiable when the prevalence reaches 7% to 8%.¹⁸ The

prevalence rate of 8% in our study is high enough to justify screening for chlamydial infection in this population, but it is still lower than that of other studies of asymptomatic populations.^{19,20}

Screening populations such as ours for gonorrhea and syphilis does not seem worthwhile. Because gonorrhea is more often symptomatic than chlamydial infection,¹⁵ it is possible that any subjects in our study with gonorrhea had already sought and received treatment before presenting for premarital examination or were among those who refused to participate. However, neither possibility was verified by questioning the applicant about previous STDs. While there were three positive tests for syphilis in our population, that these cases had already been recognized is a tribute to existing public surveillance mechanisms. The finding of two penile ulcers that otherwise would not have come to medical attention was equally surprising. Our inability to define an etiology because the patients did not follow up points to the difficulty of serving younger patients who otherwise seek medical advice infrequently.

Several cautions are in order in interpreting our data. First, the ELISA screening test used in this study is not a perfect test for chlamydial disease. The sensitivity and specificity of the chlamydial ELISA are 53% to 90% and 92% to 97%, respectively.^{14,21} Because culture for *Chlamydia trachomatis* is expensive, time-consuming, and not widely available, the ELISA antigen test has been judged more appropriate than culture for mass screening.^{22,23} The rates of chlamydial infection in the clinics within our health center are comparable to those of other studies of similar populations,^{19,20} a measure of validity of the chlamydia testing used in this study.

Second, that 37% (50/134) of our patients refused examination raises the potential of selection bias. This rate of refusal is comparable to that in a recent study of chlamydial infection in asymptomatic persons.²⁴ We are unlikely to change that proportion without legal mandate. Patients who participated in our study but who refused genital sampling

or in whom sampling was not possible appeared similar to those who permitted sampling except for the difference in educational status of the two groups (Table 1). However, it is possible that patients who refused any participation in our study (10% of the eligible population), and therefore for whom no information was available, were different from those who participated. Selection bias may have resulted because premarital applicants who were conscious of an increased risk or who were confident of being at no risk might have refused to participate in the study. Finally, our findings may not be generalizable to the population at large. Our patient population represents approximately 1% of the persons applying for marriage in our county. However, our findings do seem relevant for any community clinic that serves a population of lower socioeconomic status.

In summary, screening of premarital applicants for gonorrhea, chlamydial infection, and syphilis in this community health clinic showed that tests for chlamydial antigen were positive in 8% of subjects who allowed testing. This percentage approaches that recommended for population screening. No new cases of syphilis and gonorrhea were detected. While this evidence alone does not prove that premarital screening for chlamydial infection in community health clinics is warranted, our data support the idea that premarital applicants in community health clinics should be considered at significant risk for chlamydial infection. It is not reasonable to assure the premarital examinee in this clinic setting that sexually transmitted diseases are not present unless we have tested for chlamydial infection. □

Acknowledgements: The authors thank Abbott Laboratories for the donation of the Chlamydiazyme diagnostic kits; Abbott Laboratories had no other involvement in this study. Additionally, we thank Ms. Betty Causey and Dr. Ramon Velez for supporting the project.

Commentary

By Charles H. Livengood III, M.D., Associate Professor of Obstetrics and Gynecology, Duke University Medical Center, Durham, NC 27710.

Dr. Wofford and his colleagues have provided in the accompanying article an outstanding perspective on the subject of premarital STD screening. Their observance of the inconsistency between the assurances provided to the patient by the signature of the physician on NCDHS Form 1836 and the strength of the data to support those assurances in most cases is one that deserves emphasis. If indeed we are to make good on those assurances, then for which among the ever-lengthening list of STDs should we test?

Premarital STD screening was conceived at a time when syphilis and gonorrhea were the only two known STDs of significant prevalence in the United States. At least part of the rationale for premarital screening was that people who otherwise had little or no contact with established medical resources would present in the process of getting married, thereby offering a window of opportunity for screening; also, that the unsuspecting spouse might be saved exposure to infection when sexual contact began after the marriage. Obviously, these conditions no longer pertain.

The emergence of chlamydial genital infection, hepatitis B, hepatitis C, HIV, human papillomavirus, chancroid, and others—all representing significant illnesses—makes comprehensive STD screening a large-scale and expensive endeavor. While Dr. Wofford and colleagues have shown that testing for chlamydia was the most productive among the infections for which they tested in their population, it remains difficult to discount the importance of these other diseases.

The availability of a health department clinic in all 100 counties of this state has made mainstream health care vastly more available to all people than previously, so that the window of opportunity for STD screening occurs more often than at the time of marriage. Further, effective contact tracing programs provide for treatment of those individuals who might otherwise not present to the health care system. Also, marriage does not precede sexual contact as frequently as at the time of inception of the premarital screening concept, so spouse exposure is less likely to be avoided by such screening.

When one examines premarital STD screening in the framework of the public health, the concept becomes even paradoxical. At the time of marriage people promise to expose only one other person to any STDs they may harbor; at most other times in their lives they express no such intended limitation. It is only partially with tongue in cheek that one could suggest that more people would be protected against the spread of STD by predivorce screening than by premarital screening.

In 1974 the incidence of gonorrhea in the United States, which has been rising at 1% to 15% each year, began to decline by 3% to 5% each year. This pivotal point coincided with the implementation of the concept of presumptive treatment of gonorrhea. Presumptive treatment for STD has proven effectiveness. Further, as noted by Wofford et al, the false-negative rate with ELISA tests for chlamydia may approach 50%. In a population with a prevalence of infection of 15%, Kent et al¹ showed that use of presumptive treatment guidelines recommended by the Centers for Disease Control resulted in a higher frequency of treatment of infected persons than screening with a rapid test for chlamydial infection.

Thus, it would seem more appropriate to current conditions, more in the best interest of the public health, and more effective in the health care provider-patient relationship to offer full premarital STD screening rather than to require a vestige of it. Resources that might be saved by this approach could be invested in presumptive treatment, contact tracing, and management of high-risk populations, such as the patients identified by Wofford et al.

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FROM THE EDITOR

A Niche For the Journal

One of my most difficult jobs is explaining to doubters why a state medical society of modest size should support a medical journal. The Doubters always wonder whether we offer anything they wouldn't find anyway in *JAMA* or *AMA News* or some subspecialty journal to which they already subscribe. I think we do offer something special and that we can be proud of the tradition of scholarly communication that began here with Dr. Wingate M. Johnson in 1940. Let me offer some examples:

1. As we were writing a recent paper, my colleague Beth Belkin and I came upon the critical bit of information in a 1949 issue of the *North Carolina Medical Journal*! Without that piece of evidence, preserved in our *Journal*, our case would have been plausible but only circumstantial.

2. In this issue of the *Journal* we offer three examples of the unique niche occupied by the *NC Med J*. Dr. W. Grimes Byerly shares with us the saga of his adventures in the realm of membership recruitment, an experience made tangible by the technique of the scholar: he has collected data about what happened. Dr. Doris Iarovici continues in the footsteps of several other medical students who have worked with me in my practice. She became curious about a question raised by a patient we saw, and she has written down what she learned, continuing the case-based teaching tradition of the *Journal*.

Finally, Dr. William Howell has, like Dr. Byerly, done what few of us do—observed and quantified and then reflected on what this job of doctoring is really about. It is rare that a state medical journal will have the chance to rescue from oblivion a paper of general importance, but we are pleased to be able to do so on occasion.

None of these papers would get into *JAMA*. Enjoy!

—Francis A. Neelon, M.D.

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Continuing Medical Education

August 22

Assisted Reproductive Technology Course

Place: Chapel Hill

Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Building, Chapel Hill 27599-7000. 919/962-2118

September 10-11

Advanced Cardiac Life Support (ACLS) Retraining Course

Place: Raleigh

Credit: 8 hours, AAFP

Fee: \$75

Info: Helen Creech, R.N., Course Coordinator, Rex Hospital, 4420 Lake Boone Trail, Raleigh 27607. 919/783-3161

September 18-19

Practice Management Conference (PMC)

Place: Research Triangle Park

Info: Deborah W. Alford, Meetings Manager, NCAFP, P.O. Box 18469, Raleigh 27619. 1-800/872-9482

October 22-25

5th National Conference on Professional Well-Being

Place: San Francisco, CA

Fee: Varies

Info: Marjorie Harrison, Ph.D., Society for Professional Well-Being, 21 W. Colony Place, Suite 150, Durham, NC 27705. 919/419-0011

Continuing throughout the year Geriatric Education Modules

Place: Durham

Fee: \$10

Info: Geriatric Education Center, Box 3003, DUMC, Durham 27710. 919/684-5149

Diagnosis and Reporting of Sexually Transmitted Disease in Durham County, North Carolina

Amy Lansky, M.P.H.,¹ J. Conley Thomas, Ph.D.,² and Jo Anne Earp, Sc.D.³

One strategy for controlling sexually transmitted diseases (STDs) is to focus prevention efforts on individuals who are identified as being at high risk when they come for clinical services. Physicians rely on epidemiologic data, obtained through review of the records in a public health STD clinic or cases reported to the state health department, to identify the characteristics of individuals at high risk.¹⁻³ Public health clinics are closely tied to the state disease reporting system and are thorough in their reporting of cases. However, private physicians fail to report an estimated 60% to 90% of reportable STDs diagnosed in their practices.⁴⁻⁹ Also, the characteristics of patients visiting private physicians are likely to differ from those visiting public health clinics. Therefore, risk characteristics identified from patients who attend public health clinics or from cases reported to the state health department may not be relevant to clinicians in private practice.

We are studying risk factors for repeat STD infection in hopes of making inferences applicable to an entire community. In preparation for this study we surveyed all private and public providers of STD treatment in Durham County,

North Carolina, to identify: 1) the distribution of STD visits among the providers of care for STD; and 2) differences in the patient populations and clinic procedures among the various types of care providers.

Methods

In 1990 the population in Durham County was 181,835; 74% of the residents live in the city of Durham, where Duke University and its Medical Center are located. Thirty-seven percent of the county population is black. Epidemiological aspects of gonorrhea in Durham County have been previously described.¹⁰

The medical practices under consideration for the study were the Durham County Public Health Clinic, other community health centers treating low-income patients, a health maintenance organization, the Duke University Medical Center emergency room, an urgent care center, and all private practices likely to treat STDs. The medical practices were identified from the North Carolina Medical Society membership list and the local telephone book. Private

practices selected for the study were those specializing in general private, family practice, internal medicine, obstetrics, gynecology, urology, dermatology, or pediatrics. Non-practicing physicians and those whose primary affiliation was with Duke University were excluded.

Medical practitioners were contacted by telephone from June 1990 through September 1990 and asked to respond to a five-minute survey. Providers who could not be contacted by telephone were mailed a questionnaire. Responses were solicited from the office manager when a physician was unavailable to provide the requested information. The survey solicited information on characteristics of the medical practice, patient demographics, referral procedures for STD in the past year, and the reporting and diagnosis procedures for gonorrhea and syphilis. The definition of an STD visit was left up to the provider, and variability in definitions is likely. Respondents were asked to estimate the numbers of patient visits when exact figures were not readily available to them.

The data are presented for three types of medical practice: 1) the county public health clinic, 2) private practices, and 3) community clinics. Community clinics

From the ¹Division of STD/HIV Prevention, National Center for Prevention Services, Centers for Disease Control, Atlanta, GA., the ²Department of Epidemiology, School of Public Health, University of North Carolina, Chapel Hill, NC, and the ³Department of Health Behavior and Health Education, School of Public Health, University of North Carolina, Chapel Hill, NC. Funding for this study was provided in part by the North Carolina Medical Society.

Table 1. Characteristics of STD Care Providers in Durham County

Provider Characteristics	Type of Provider		
	Public Health Clinics (n=1)	Community Clinics (n=5)	Private Practices (n=26)
Estimated mean number of STD visits per week	330	45	175
Percent of non-white patients	80	56	33
Percent of patients 18 to 25 years old	35	23	33
Percent of 18- to 25-year-old patients who are male	50	34	31

were defined as those practices apart from the public health clinics but not privately run. The Duke University Medical Center emergency room was included in this category.

Results

Forty-one medical practices treating STD were identified in Durham County. Five (four of which were internal medicine practices) declined participation in the study. An additional four could not be contacted by telephone and did not return mailed questionnaires. Included in these four was the health maintenance organization. Thus, a total of 32 providers (78% of those eligible) completed the survey. These included five community clinics and 26 private practices (Table 1).

These Durham County providers reported attending to a mean total of 550 patients for STD each week in the past year. The majority of patients (62%) were seen by the public health clinic, 30% by private physicians, and 8% by community clinics (Table 1). Thus, about 40% of STD visits in our sample of Durham County were to private or community clinics. Visits to the practices that declined participation in this study presumably would have increased the percentage of patients seen in non-public health clinics.

Although about 80% of the STD patients visiting the public health clinic were black, the majority of patients (67%) in the private practices were white. The ethnic mix of patients in the community clinics fell between these two extremes.

The percentage of patients aged 18 to 25 years was similar in the public health clinic and the private practices (about 35%). However, in the public health clinic, a larger percentage (50% versus 31%) of these young patients were male.

The public health clinic accepts all patients regardless of their ability to pay for services. More than half (58%) of the private practices and 40% of the community clinics reported accepting some patients who relied on Medicaid, but these usually composed fewer than 10% of the patients seen in the practice.

The public health clinic diagnosed all STD patients on site, using both smears and cultures to diagnose gonorrhea and the VDRL (Venereal Disease Research Laboratory) test to diagnose syphilis. All diagnosed reportable STDs were reported. Four (80%) of the community clinics obtained specimens for gonorrhea cultures and sent them to a laboratory for diagnosis. The remaining clinic performed its own cultures. For diagnosis of syphilis, all sent specimens to a laboratory for the VDRL test. Since most speci-

mens were analyzed in outside laboratories, positive results would be reported by the laboratories. The one clinic performing its own cultures claimed to report all diagnosed cases.

Private practices were more variable in their ability to adequately diagnose and report STD (Figure 1, opposite). An inadequate diagnosis was defined as one based on symptoms alone, or on only a smear for gonorrhea diagnosis. Data on diagnosis and reporting were available for 25 of the 26 private practices. For diagnosis of gonorrhea, five (20%) and for syphilis, four (16%), of the private practices offered no collection of specimens and referred patients elsewhere for diagnosis, usually to the public health clinic or the Duke University Medical Center emergency room. All private practices sent specimens for VDRL or RPR (Rapid Plasma Reagent) testing to an outside laboratory.

Nine (45%) of the 20 practices that offered gonorrhea testing had diagnostic facilities on site. Of these, six diagnosed on the basis of culture and three used only smears. Only five of the nine practices diagnosed any cases of gonorrhea in the past year; three (60%) of these admitted to underreporting diagnosed cases.

Discussion

As of fall 1991, the state health department recorded 808 cases of gonorrhea from Durham County for 1990. Of these, 132 (16%) came from private and community practices. In the absence of disease-specific data for patient visits, we assume that gonorrhea cases are distributed between public health and non-public health practices in the same proportion as STD visits (40% in non-public health). Thus the number of cases reported by private and community practices appears low, reflecting underreporting. Twenty-one (31%) of 67 syphilis cases reported from Durham County to the state came from private and community practices. Under the same assumption of similar distribution of cases, this reflects less underreporting for

syphilis by these practices. The degree of underreporting may be exaggerated in this study, since gonorrhea and syphilis may not be equally distributed among types of practices. However, these estimates underscore the fact that a significant amount of STD is seen in the private sector.

Collection of serologic specimens for laboratory diagnosis of syphilis was offered by nearly all private and community practices. This may be due in part to the common practice in North Carolina of obtaining syphilis testing before marriage (see article on premarital STD examination on page 421) and to testing for some employment physicals. Virtually all private and community practices sent syphilis specimens to outside laboratories for analysis. Laboratories, like physicians, are required to report positive specimens of reportable STD, but do so more thoroughly than physicians.⁵ As a result, underreporting of diagnosed syphilis is likely to be infrequent.

Diagnostic and reporting practices for gonorrhea were more variable. Private practices analyzing their own specimens may account for a large proportion of underreported diagnosed gonorrhea cases. In a study of North Carolina Medical Society (NCMS) member physicians throughout the state, 13% of those diagnosing gonorrhea stated that they do not report all diagnosed cases (Conover CJ, Weinberger M, unpublished data). In our study, the proportion not fully reporting was considerably higher (60%). Inadequate diagnostic procedures may contribute to underreporting. Twenty-five percent of the NCMS members reported that they did not refer or collect a clinical specimen on all suspected cases of gonorrhea (Conover CJ, Weinberger M, unpublished data).

In studies of public health clinic records and cases reported to the state health departments, individuals at highest risk for reinfection have been young, non-white, men of low socioeconomic status.¹⁻³ This information is relevant to clinicians in public health clinics who wish to focus education efforts on high-risk individuals. However, such charac-

terizations are made largely in the absence of information on patients visiting private practices. Patients seen in Durham County private or community practices were less likely than those seen in the public health clinic to be black, and those aged 18 to 25 years were less likely to be male.

Patients using Medicaid, suggesting lower socioeconomic status, were seen less frequently in the private practices. Since 40% or more of Durham STD patients were seen outside the public health clinics, a profile of risk for STD that is derived exclusively from public health clinic patients is not likely to accurately reflect the total patient population in Durham County. For example, young black males of lower socioeconomic status visiting community clinics may not share the same risk for reinfection as their counterparts visiting the public health clinic. The risk for reinfection among some private patients, such as white females, is not known; in addition, those

patients may be at risk for non-reportable STD.

Estimates of the number of STD visits and related patient demographics recalled by clinic staff for this study may differ significantly from actual numbers. However, our findings are consistent with previous studies indicating that private physicians are more likely than clinicians in public health clinics to use inadequate technique in diagnosing STD and to underreport diagnosed cases.¹¹⁻¹³ These two issues have implications for epidemiologic research and STD control.

The incentives for private physicians to report are not immediately evident; therefore, epidemiologists aiming to identify risk factors for the entire community—rather than just one sector of it—need to obtain reliable information on STD among patients in both private and community clinics. In this way, guidelines for disease prevention that are of value to clinicians in these practices can be developed. □

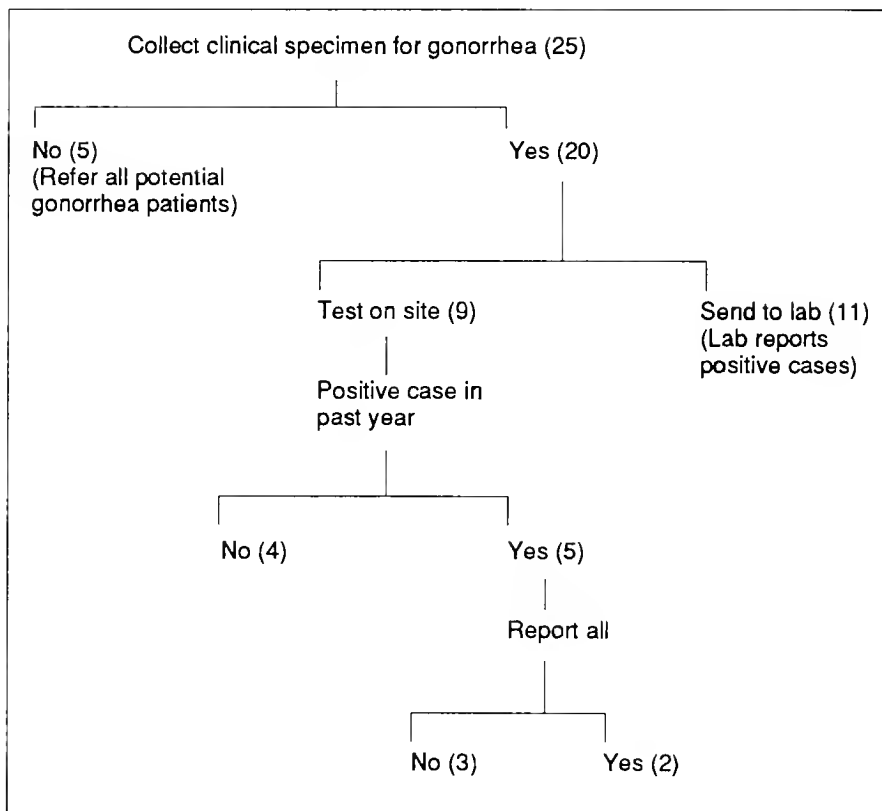


Figure 1: Gonorrhea diagnosis and reporting among 25 private practices in Durham County, 1990.

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M&Ms

Membership and Medicine

W. Grimes Byerly, M.D., F.A.C.S.

"A man may be taught but he does not necessarily learn."

—Homer

I have been a member of the North Carolina Medical Society's Membership Committee for several years. In that capacity, I, along with many other physicians, have participated in Dr. 'Buddy' Garrett's continuing saga of "Men and Women for Medicine." This has meant personal contact when possible, occasional local telephone calls, some letter writing and, in recent years, the interesting annual phone-a-thons. Despite this activity, however, I confess that I never truly knew whether, one-on-one, I was accomplishing anything.

Then, in 1989, the Medical Society Leadership created the Peer-to-Peer Membership Recruitment Campaign. Last fall the present campaign started at the annual meeting in Asheville. Sixty-five delegates and non-delegates took the names of non-member physicians from their district and committed to approaching each non-member personally about joining the Medical Society. Each recruiter was given the necessary recruitment materials including information about Society accomplishments and benefits. Newly recruited members who submitted 1992 dues by March 31, 1992, were to be counted as successes by the campaign.

During the course of the House of Delegates deliberations, Doctors Garrett and [Richard] Bruch reminded all present of the campaign and of the necessity to recruit (and retain) new members. I made a special effort to stop at the Medical Society staff desk as I left the meeting. Grouped together under the 15th District, which included my own county, was a stack of papers obviously related to individual physicians—statistics, application cards, society information, etc. I thumbed through the papers quickly thinking to take a few whom I recognized immediately. I would see them in everyday life at my hospital. Then I thought, "What the hell, I'll just take the entire batch and see what I can do." After all there were five months to go and that would be plenty of time!

From the Medical Arts Clinic, 24 Second Ave., N.E., Hickory, NC 28601.

Now, as the Peer-to-Peer Campaign has come to a close, it seems worthwhile to set down some of the pitfalls, stumbling blocks, and final results encountered during one man's effort. What follows is a brief tale of the tribulations of personal membership recruitment.

The Challenge of Recruitment

I arrived home from the annual meeting to resume my active surgical practice. I stacked the papers on a shelf next to my office desk. Then a long weekend vacation; later, the Thanksgiving holidays. Suddenly only four months to go! (Procrastination is the first pitfall of the recruiter.)

I had taken 30 names. I thought to myself, "Now I've been involved in this business for some years, why not at this time give this competitive campaign a real 'do-or-die' effort just to see what happens?"

It is interesting how 30 names—30 physicians whom I thought I knew reasonably well—could be so diverse! I thought, "We are all 'doctors' in the broad humanitarian sense of the word. I am not really going to attempt to sell these people some product or service that is completely unknown. We are all in the same line of business! I am not selling my personality or proving my sales ability. I am merely following up regarding what we are all involved in, namely organized medicine—whether we like it or not, whether we support it or not." (Overconfidence is the second potential pitfall of the recruiter.)

The Tribulations of Recruitment

Of the original 30 physicians on my list, two had moved completely away from the area during the preceding year. This was a surprise to me and was unknown to the people keeping our

society's mailing list. Down to 28 for actual starters.

I was never able to ascertain exactly who or where two physicians were. During the time covered by this report they were not on any of the three hospital staffs in my district, never showed up at meetings, and I was unable to obtain their addresses or telephone numbers. By the time the campaign was over I still had not solved their identity status. Down to 26 that I could possibly recruit.

Working in three communities, at three hospitals, and with numerous group practices, I decided to first approach those physicians who worked at my own hospital and whom I could easily (?) contact. (Thinking everyone else keeps your schedule is the third pitfall of the recruiter.)

One of the seven member group practices already had four of its doctors in the society, and therefore only the three on my list were to be the challenge. I elected to use person-to-person (eyeball-to-eyeball), five-minute chats. Because the doctors worked different shifts on different days, I had to accommodate and catch them as best I could. I became involved in their P.A., Inc., "Perk System." They couldn't see me because they had to "meet with their associates," "with their managers," "maybe next week," etc. December got used up with a lot of vacations and people not available, then came the first of the year with holidays. (Believing that doctors work all the time is the fourth pitfall of the recruiter. I came to wonder that some worked at all!)

Nevertheless, after 60 days or so, I had contacted or somehow accounted for all of the names on my list. (Three more months to go—plenty of time?) By January's end, I had weeded out the really definite "No's" (Table 1, #1-3); had promises (to me) from the "Yes's;" and had lined up the "Maybes." The tally: No - 3; Yes - 12; Maybe - 11. Not too bad I thought. (Believing that all physicians are like surgeons—definitive and immediately decisive—is the fifth pitfall of the recruiter.)

At the end of February, with one month to go, my group of 12 "Yes's" became 9 when the headquarters staff took count; the "Maybes" had increased to 14. I re-contacted all 14 for another personal go-round in the recruiting process. Another one moved into the "No" column. By the end of the fifth month, four more had moved into the "No" category (Table 1, #4-8):

At the end of my work, after repeated personal contact, re-contact, sending informational literature, etc., there were nine "Yes's" and eight "Nos." I considered that six remained in the "Maybe" category but these six indicated "definitely" (so it seemed to me) that they would join before March 31; three did. Three doctors on my original list never responded to my queries, telephone calls, medical society notices, etc.; two could not be identified; and two had moved away before I began. The final accounting, using headquarters data on who actually paid dues, is shown in Table 2.

It would be nice if there were some rule or regulation that required every physician to be a three-component member (i.e., of the county, state, and national societies). We would have plenty of income and could lower our dues drastically all along

the line. Or if we could make membership an obvious financial advantage for physicians we would have a lot more members. However, in the present environment, there is no better means of recruitment than doctor-to-doctor, peer-to-peer contact, and I strongly support the Medical Society's efforts along this pathway. I believe that my report demonstrates the effectiveness of this approach: Thirteen (12 Yes's and one Maybe who enrolled after the campaign) of the original 30 doctors on my list (43%) eventually joined the Society; more than half (13 of 23) of the doctors I was actually able to see in person joined. I strongly encourage all of you to work with the Medical Society in this endeavor. And I have suggested five potential pitfalls for physician recruiters that should help you on the way. □

Table 1. Why the Doctors Said "No."

- 1) Absolutely NOT ("Grimes, I told you 'No' two years ago and the answer is still 'No'! Good day!"). This from a long-time, busy, and highly respected specialist who is strongly motivated by anti-organized medicine sentiments. (I haven't been able to overcome those in four years!)
- 2) No, because this doctor's wife is a member and they can see no reason to pay twice.
- 3) No, basically because of anti-organized medicine sentiments and the opinion that the Medical Society does "nothing for me." (This opinion in spite of all the information I can give him, and the urging of his partners and physician father!)
- 4) No, because of ideology regarding the abortion issue. The physician is adamantly anti-abortion and perceives the Medical Society as pro-abortion. Except for this single issue, he has no problems with county, state, or national organizations.
- 5) No, because the Medical Society is "not doing much for me" (his specialty society is more important), plus the expense of the state and AMA dues. (He belongs to the county society).
- 6) No - basically as #5.
- 7) No - the monetary cost is more than the benefit.
- 8) No - ditto.

Table 2. Final Status of 30 Potential Members

Category	Number
Yes	12
No	8
(Organized medicine "not doing anything for me")	4
(Too much money)	2
(Double coverage with spouse)	1
(Ideological disagreement)	1
Maybe (one joined after the campaign)	3
No response	3
Moved away	2
Couldn't be located	2

Membership Committee Members Comment

The *Journal* invited comment on Dr. Byerly's article from two physicians active in member recruitment for the North Carolina Medical Society: Richard F. Bruch, M.D., of Triangle Orthopaedics Associates, Durham, chairman of the Medical Society's Membership Committee, and Andrew Wm. Walker, M.D., of the Charlotte Plastic Surgery Center, Charlotte, a member of the Medical Society's Membership Committee.

Dr. Grimes Byerly has demonstrated the North Carolina Medical Society experience concerning membership recruitment. Potential members respond positively to direct contact by a physician member. The Society's two most effective membership efforts have been the Peer-to-Peer Campaign and the Phonathon. The Peer-to-Peer Campaign involves direct membership solicitation of non-members from the solicitor's locale. The Phonathon involves "cold calls" made by volunteer physician members calling from the North Carolina Medical Society headquarters. Our ongoing letter-writing campaigns to non-members have not been nearly so successful.

The North Carolina Medical Society is the most effective organization to which I belong. It does a tremendous job of representing physicians and our patients. This effectiveness must be transmitted to non-members, especially the younger physicians. They are under-represented in our Society.

There is full value received for the dues paid. No specialty organization duplicates the efforts of the North Carolina Medical Society. A disagreement over one issue, such as abortion or RBRVS, should not outweigh all the other advantages of supporting this most effective society.

Clearly the task of recruiting new members lies in demonstrating to ourselves and to them that the North Carolina Medical Society is an open and vibrant organization that represents not only physicians but our patients.

Membership recruitment is an ongoing task best performed by our members taking the initiative to directly invite others to join the "House of Medicine."

*Richard F. Bruch, M.D.,
Chairman, Membership Committee
North Carolina Medical Society
Triangle Orthopaedics Associates
2609 N. Duke St.
Durham, NC 27704*

Dr. Grimes Byerly has written a good article, one that should provide food for thought and should encourage all of us in our efforts to strengthen the North Carolina Medical Society. Increasing our membership has to be a priority in this task. In particular, I offer the following comments:

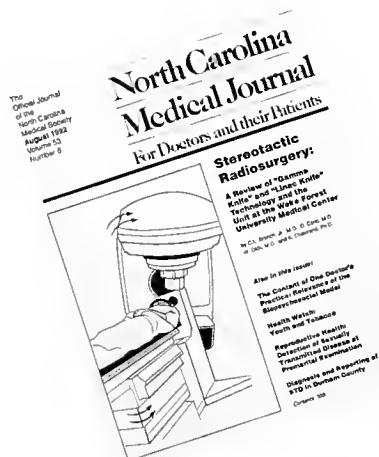
1. We cannot force any doctors to join us, but perhaps we could use the Society seal or logo to identify ethical, responsible, caring doctors. We would need an education program in the state to promote the significance of such a seal or logo to the public. Then, when the seal or logo is not displayed, patients may ask why not.
2. We could offer discounts to groups when 90% of the group members join the Society. This encourages the entire group to join. Similarly, we could offer discounts when both husband and wife physicians join.
3. We need to ensure that nonmembers in a group do not take advantage of the benefits provided to the members of that group.

These thoughts of mine will need discussion and reflection, and others may add more. But all of us need to pay attention to Dr. Byerly's advice: Nothing succeeds like personal contact from a member of the Society who is known and respected. We all need to work at that.

*Andrew Wm. Walker, M.D.
Member, Membership Committee
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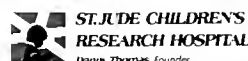
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Aphorisms of the Month

Edited by Daniel Sexton, M.D.

Success and Failure*

Trifles make perfection and perfection is no trifle.
—*Michelangelo*

Success is never final. Failure is never fatal. It's
courage that counts.
—*Winston-Churchill*

Finish every day and be done with it. You have done
what you could. Some blunders and absurdities no
doubt crept in; forget them as soon as you can.
Tomorrow is a new day; begin it well and serenely
and with too high a spirit to be cumbered with your
old nonsense. This day is all that is good and fair. It
is far too dear with its hopes and invitations to waste
a moment on the yesterday.
—*Ralph Waldo Emerson*

Meet with triumph and tragedy and treat those twin
impostors the same.
—*Rudyard Kipling*

Once you have established the goals you want and
the price you are willing to pay for success, you can
ignore the minor hurts, the opponent's pressure and
the temporary failures.
—*Vince Lombardi*

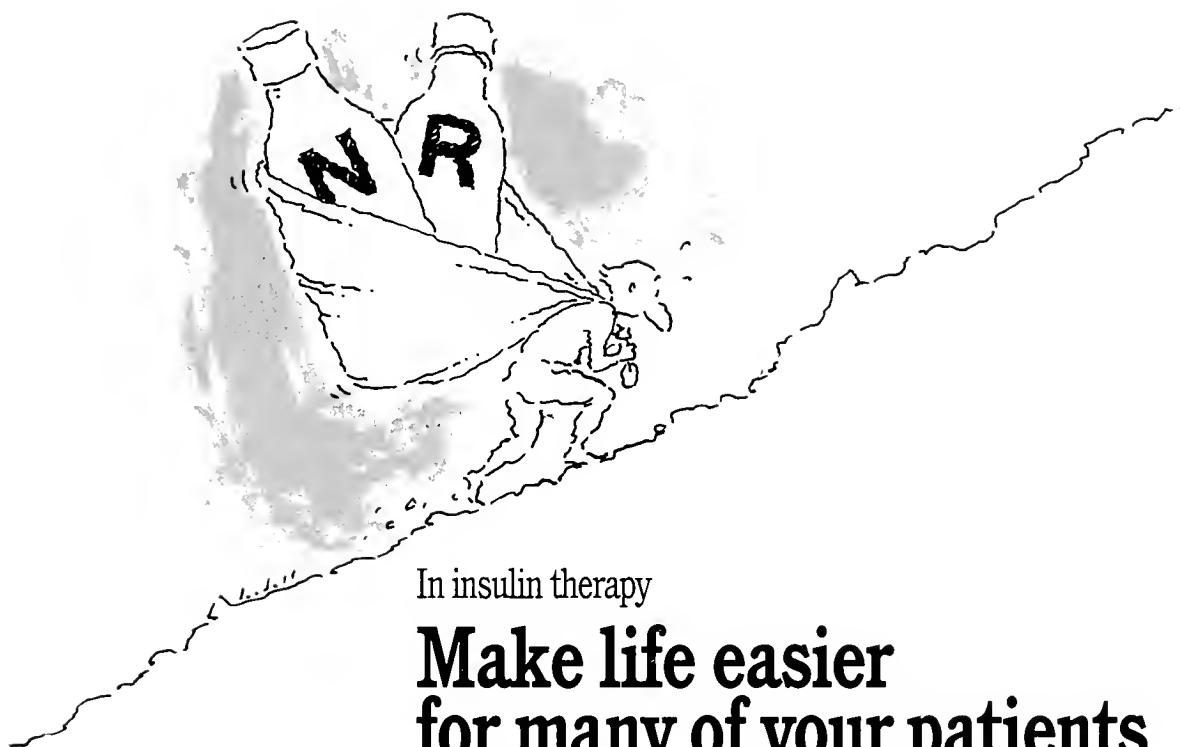
The man who makes no mistakes does not usually
make anything.
—*Edmund J. Phelps*

You don't drown by falling into water but by
staying there.
—*Robert Cavett*

* Selected from aphorisms submitted by William J.
Mallon, M.D., Duke Univ. Medical Center, Durham.

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North Carolina Medical Journal

For Doctors and their Patients



Prostate Cancer in North Carolina

by Cary Robertson, M.D., Wendy Demark-Wahnefried, Ph.D., R.D., and Tim Aldrich, Ph.D., M.P.H.

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For Doctors and their Patients

Published Monthly as the Official Organ of the North Carolina Medical Society

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North Carolina Medical Journal

FOR DOCTORS AND THEIR PATIENTS

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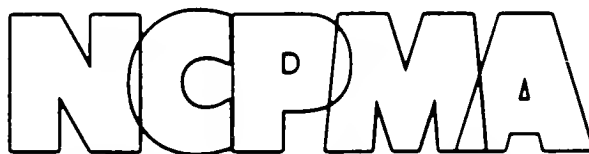
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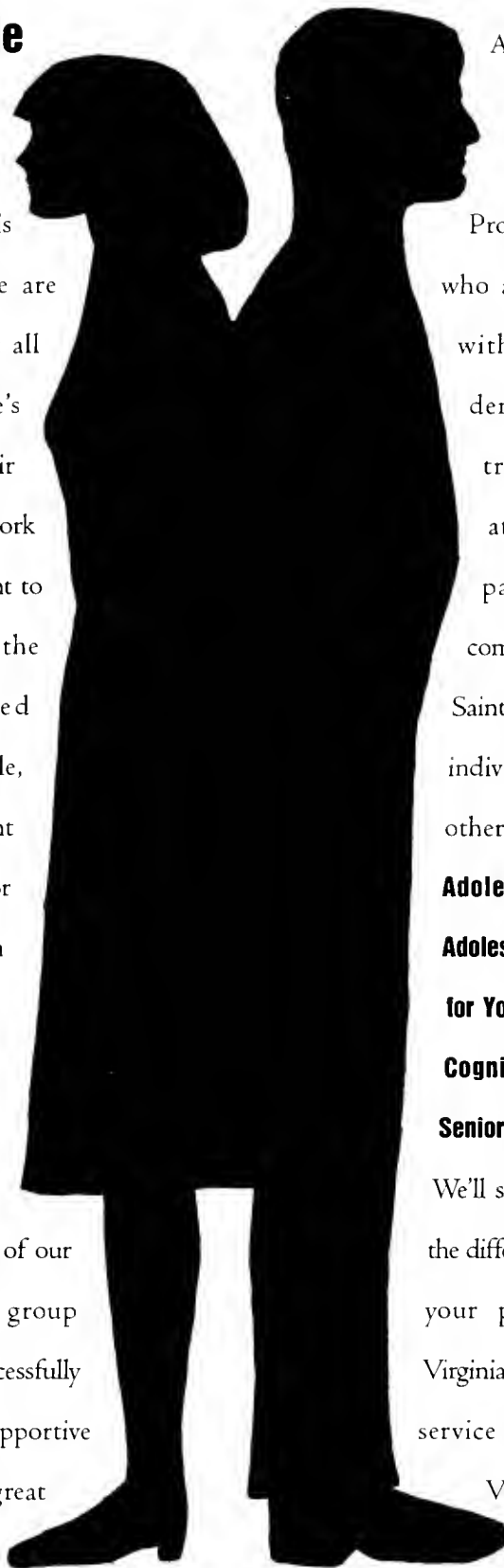
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Letters to the Editor

Supports Lawyers' Ad

To the Editor:

I missed the original advertisement by the law firm, Smith Debnam Hibbert and Pahl, (NC Med J 1992;53:211), but I have read the multiple letters in the July issue and your editorial in the June issue. It seems appropriate that we might take another look.

I am sure that many of us have cared for patients who have suffered significant personal injury for which they are contractually due compensation to pay their physician's bills and other medical expenses and to compensate them for loss of income and for pain and suffering. Usually this contract is with an insurance company that is generally most interested in minimizing its obligation. Appropriate and vigorous legal assistance in these circumstances is often not only appropriate, but necessary.

Fortunately, I know well several members of the bar in our community and I feel considerable comfort in recommending their services as counselors and problem solvers. I feel certain that they will represent their clients, with litigation as a last resort. If Smith Debnam Hibbert and Pahl wish to try to let us know that this is their position, such an advertisement should not be banned from the *North Carolina Medical Journal*.

It would certainly behoove such an advertiser to be quite sensitive to the tremendous anxiety that we physicians feel, because our every act in patient care is so subject to legal review and scrutiny. The last I heard, lawyers were not subject to being sued for malpractice for their actions in the courtroom because the pressure there was so great that they should not be subjected to second guessing. When lawyers decide to apply the same standard to physicians, I shouldn't be at all surprised if a great deal of our reflex animosity dissipates.

John R. Dykers, Jr., M.D.
P.O. Box 565
Siler City, NC 27344

Treating Anaphylaxis

To the Editor:

There are more deaths from allergic reaction to insect stings than from snake and shark bites combined. Most people do not realize this nor do they know the necessary emergency treatment. Death from allergic reaction can occur within five minutes. This is insufficient time to get to a physician or hospital.

I appeared before the NIH and the AMA and was able to

influence the AMA to prepare a model bill to legally allow trained laypeople, such as schoolteachers, rescue squad workers, recreational facility workers, and law enforcement officers, to administer epinephrine injections (1:100) to anyone suffering anaphylaxis due to an insect sting. The state of North Carolina has made this into law. However, these laypeople must be trained by a physician. It appears most physicians and non-physicians do not know about this and should be informed.

I have put together a simple training program, complete with slides, which I have been conducting in my area free of charge. I am willing to share this training program with physicians wishing to conduct training sessions in their area. For information please write me at: Dr. Claude A. Frazier, Doctor's Park, Bldg. 4, Asheville, NC 28801.

Claude A. Frazier, M.D.

Tetanus Toxoid vs. Tetanus Antitoxin

To the Editor:

Physicians have not been telling their patients the difference between tetanus toxoid and tetanus antitoxin serum. I constantly ask my patients about their immunization records. One question I have asked is "Have you received tetanus toxoid?" The universal reply is, "I don't know. When I stuck my foot with a nail, they just gave me a tetanus shot." They don't know whether it was tetanus toxoid or tetanus antitoxin. I think doctors should tell their patients which immunization they have received.

Claude A. Frazier, M.D.
Doctors Park, Bldg. 4
Asheville, NC 28801

From the Editor:

Dr. Frazier's letter touches on the prickly subject of communication and the difficulties in achieving it. If the information he desires (whether the injection was of tetanus toxoid or of anti-toxin) is important to the care of patients, then we doctors ought to find a way to preserve the data for the patient. However, most studies of information transfer from doctor to patient show that patients cannot even remember that they have been told something, let alone what they were told. It seems doubtful that another admonition that "doctors should tell their patients" would result in patients who know, years later, which "shot" they got.

Francis A. Neelon, M.D., Editor
North Carolina Medical Journal

The Editor's Shadow

To the Editor:

The editor's shadow fell across my last letter to the editor (NC Med J 1992;53:325). While I have no problems with an editor editing, including my stuff; another deletion was needed. The offending words referred to a deleted section of a previous paragraph and made no sense in the published revised version.

Certainly the changes made were to improve clarity, prune length, and make this little piece a little better. I am, however, a bit embarrassed that these few words remain. Perhaps no one else will notice.

If we are to encourage good writing, we need to encourage precise editing even in "little" matters.

To all the worry-warts out there, this is an intellectual friendly discussion!

Margaret Nelsen Harker, M.D.,
NCMJ Editorial Board Member
P.O. Drawer 897
Morehead City, NC 28557

From the Editor:

In her original letter, Dr. Harker mentioned two colleagues, one of whom had sent her the book, *The Elements of Style*, by Strunk and White. Because of space constraints, we cut references to these colleagues. She went on to recount her father giving her Goodman and Edwards' book, *Medical Writing: A Prescription for Clarity*, a section that we did not cut. Although we often edit letters for clarity and space, sometimes efforts in the name of word economy fall short of the writer's intent.

Worth Reading

To the Editor:

What a great piece in the August *Journal* on membership (NC Med J 1992;53:431-3)! It will open some eyes. The responses from Drs. Bruch and Walker were right on target and reinforced some important observations.

George E. Moore, Executive Vice President
North Carolina Medical Society
222 N. Person St.
Raleigh, NC 27611

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Prostate Cancer in North Carolina

Cary Robertson, M.D.,¹ Wendy Demark-Wahnefried, Ph.D., R.D.,² and Tim Aldrich, Ph.D., M.P.H.³

The Scope of the Problem

Cancer of the prostate is the most commonly diagnosed cancer of men in the United States.¹ Currently, one out of 11 men throughout the nation will develop this disease, and one third of them will die from it.¹ And as the U.S. population ages, prostate cancer will pose even more of a threat. By the year 2000, it is projected that "our country will see a 37% increase in prostate cancer deaths and a whopping 90% increase in new cases per year."²

These projections have particular ramifications for the southeastern United States where the impact of prostate cancer is already pronounced. Although Southern incidence rates tend to be slightly higher than for the nation at large, a clear discrepancy exists between national mortality rates and those in the Southeast.³ Notably high rates, particularly among blacks, are attributed to a lack of access to services for cancer prevention, diagnosis, and treatment.³

In North Carolina, 3,104 cases of prostate cancer were diagnosed in 1990—an incidence rate of 107.3/100,000 compared to the national rate of 102.3/100,000 (Table 1).⁴ Counties with the highest rates of incidence are scattered throughout the state, indicating that prostate cancer is a widespread problem and not confined to any particular region. Markedly high age-adjusted incidence rates are seen in

Forsyth, Gaston, Lincoln, Macon, and Rutherford counties (Figure 1, next page).

High incidence rates in a county like Forsyth may be a reflection of a major diagnostic center located there. In contrast, high incidence rates in western counties may be due to the exaggeration in rates that occurs when counties are sparsely populated (incidence rates = reported cases ÷ population at risk). Similarly, we must be cautious in interpreting very low rates (shown in Figures 1 and 2, next page, as lightly shaded or unshaded counties) since incidence rates may be underreported in rural counties that have limited access to screening and diagnostic services.

The map in Figure 2 illustrates county mortality. Data collected from 1986 to 1990 as part of the Surveillance Epidemi-

ology and End Result (SEER) Program show that high mortality rates are also scattered throughout the state, but Edgecombe, Macon, Madison, and Yadkin counties report markedly high rates. Again, sparse populations in some of these counties may affect their classification. The most distinguishing aspect of North Carolina's mortality data is the discrepancy between non-white versus white rates. In this state, the mortality rate for blacks is more than double that for whites—in fact it is the highest in nation!

Stage at diagnosis is, most likely, a key factor contributing to the mortality differences seen between races (Figure 3, page 449). Significantly more blacks have advanced disease at initial diagnosis. Indeed, if we are to reduce mortality in this population, it is of utmost importance to

Table 1. National and North Carolina rates of prostate cancer incidence and mortality

Incidence (per 100,000)	U.S.	NC	Significance
All	102.3	107.3	n.s.
White	101.2	103.3	n.s.
Black/Non-White	137.0	126.9	n.s.
Mortality (per 100,000)			
All	24.4	23.7	n.s.
White	22.7	23.2	n.s.
Black/Non-White	47.2	57.0	p < 0.05

From the ¹Division of Urology, Duke University Medical Center, Durham 27710; ²Cancer Control Research, Department of Community and Family Medicine, Duke University Medical Center, Durham 27710; and the ³Department of Epidemiology, University of North Carolina at Chapel Hill, Chapel Hill 27599-7400.

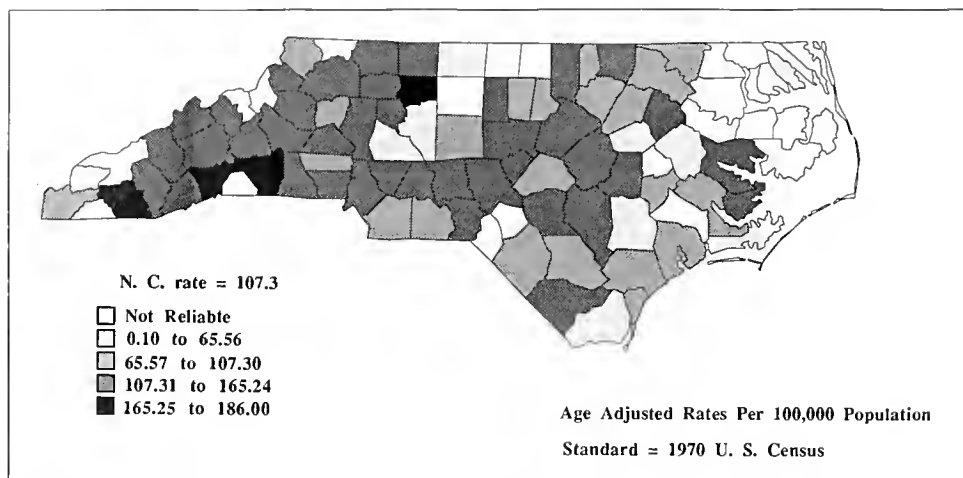


Figure 1: Incidence of prostate cancer in North Carolina in 1990 (cover map).

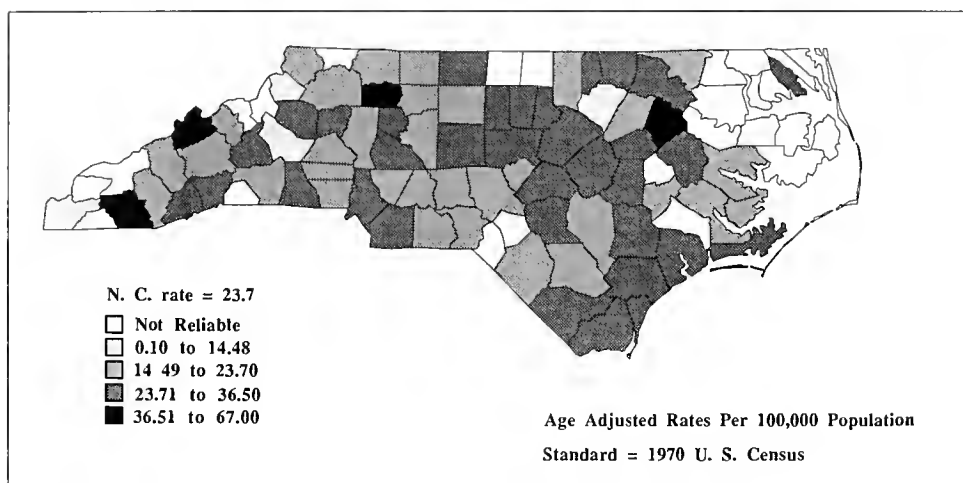


Figure 2: Mortality of prostate cancer in North Carolina from 1986 to 1990.

educate blacks about the importance of screening and to provide access to screening services.

Risk Factors

The etiology of prostate cancer is essentially unknown, but a few risk factors have been identified, including older age, black race, positive family history, and, to some extent, dietary fat intake.

Age. Prostate cancer risk increases faster with age than that for any other form of cancer. Few men develop this disease before age 50. After 50, incidence and mortality rates skyrocket almost exponentially. Median age at diagnosis is 72.⁵

Race. Black Americans have the highest incidence of prostate cancer in the world, and mortality rates are double to triple that of U.S. whites at all ages. Prostatic carcinoma, which accounts for 25% of all cancers in African-American men, is reportedly uncommon in most African nations.⁹ Indeed, African blacks have one of the lowest rates of prostate cancer in the world, indicating that environmental factors may play a major role in the development of this disease.⁵ Studies tracing the development of prostatic cancer in men who have migrated to the United States from countries of low incidence (for example, Africa and Japan) support this premise and indicate that the risk of developing prostate cancer increases significantly with the number of years spent

in the United States.^{6,7} This parallels a similar trend for breast cancer.

Family History. Pedigree analysis indicates that risk for prostate cancer is 3 to 4 times greater in men with first-degree relatives who have had this disease.⁵ For men whose family history of prostate cancer spans two generations, a nine-fold increase in risk is reported.² Prostate cancers that run in families tend to be more aggressive and more likely to strike at earlier ages.² In addition, an association between prostate cancer and family history of breast cancer has also been reported, with relative risks of 2.01 to 2.33 reported by Thiessen, et al and Cannon, et al.^{8,9} Although familial associations are indeed powerful predictors of the development of prostate cancer, it is unclear whether genetic or environment factors play the major role.

Dietary Factors. The role of nutrition in the etiology of cancer has become increasingly apparent and "of the several environmental risk factors for prostate cancer that have been proposed, the strongest evidence pertains to diet."¹¹ To date,

the dietary factor that has consistently shown a strong association with prostate cancer is fat intake.¹⁰ Epidemiological studies indicate strong positive correlations (.69 - .89) between the per capita consumption of fat and the incidence and mortality rates of prostate cancer.¹⁰ Although the strongest correlations are for prostate cancer and total fat intake, significant positive associations have been reported for saturated fats from animal sources and, to a lesser degree, for polyunsaturates.^{10,11}

In contrast, case/control studies suggest that omega 3 fatty acids may exert a protective effect, but this topic needs more study.¹² Dietary fat may contribute to the etiopathogenesis of prostate cancer through its impact on cell membranes

and its potential to mediate hormonal and prostaglandin-related events,¹⁰ but these mechanisms are speculative. No firm conclusions can be drawn about the contribution of other dietary factors, such as retinoids, fiber, vitamin C, and zinc, and the development of prostate cancer, since research has either produced conflicting results or is in its preliminary stages.¹⁰

Other Factors. Several other risk factors for prostatic cancer have been proposed, but research on the role of cadmium (primarily occupational exposure) and sexual activity has given conflicting results.¹³ Investigation into the association between anthropometric factors, physical activity, vasectomy, and benign prostatic hypertrophy is incomplete, thereby precluding any firm conclusions.¹³

Screening Guidelines

"Because the survival rate of men with tumor spreading beyond the prostate is substantially diminished compared to [that of] men with localized disease, efforts to decrease the mortality rate of prostate cancer have been directed toward early detection."¹⁴ The National Cancer Institute and the American Cancer Society have both issued screening guidelines that recommend annual digital rectal exams for men over the age of 40. Physicians are advised to exercise judgment with regard to these guidelines and modify requests for additional tests such as measurement of Prostate Specific Antigen (PSA) in blood or prostate ultrasound based on assessment of patient risk and comorbidity factors.¹⁵

Screening Strategies

In addition to digital rectal examination, our ability to detect prostate cancer has been greatly enhanced in recent years by the widespread application of serologic testing (PSA), ultrasound examination, and automatic biopsy gun techniques. Current autopsy data suggest that nearly 30% of 50-year-old men harbor microscopic foci of prostatic adenocarcinoma.¹⁶ Since only about 1% of these men will develop clinically significant prostatic malignancy in their lifetime, it appears that most well-differentiated, small prostatic carcinomas have favorable long-term prognoses and may not warrant ag-

mented, positive effect on patient survival.¹⁸ It is attractive to envision mass screening leading to detection at an early stage of malignancy and thus altering mortality from prostate cancer.

To date however, there are no randomized trials evaluating the impact of screening on the general male population. Thus, the impact of mass screening on prostate cancer mortality is unproven. Efforts are underway however to complete such a trial under the direction of the National Cancer Institute through the Prostate, Lung, Colon, and Ovary Cancer Screening (PLCO) Trial. Until definitive data are available from this trial, the most feasible strategy for prostate cancer de-

tection must be based on regular digital rectal examination of the prostate and measurement of blood PSA levels.

We believe that, for men 50 and over, PSA testing should be done on an annual basis. PSA is a serine protease produced specifically by the prostatic ductal epithelial cells. Normally, the

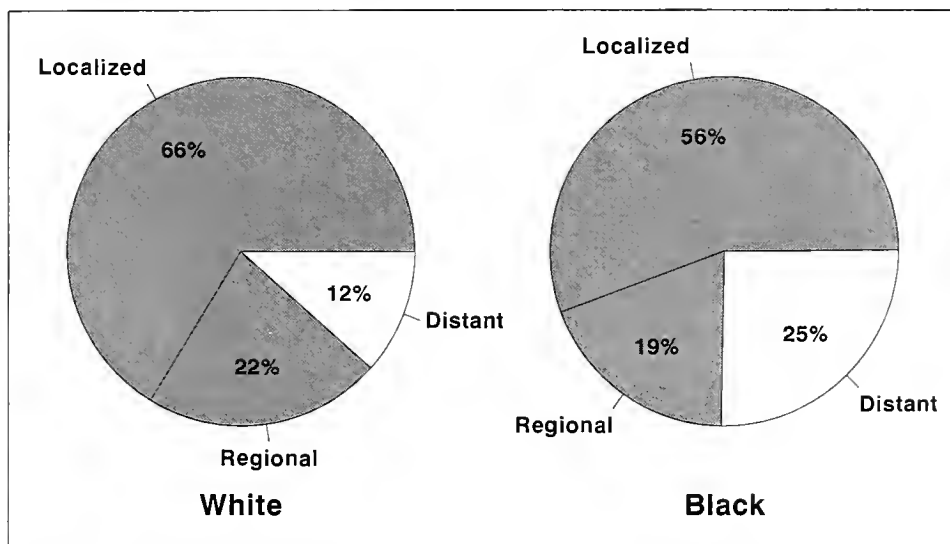


Figure 3: Stage at diagnosis

gressive intervention. Yet, some small tumors are quite aggressive and significantly affect patient well-being and survival. At present, no distinguishing features, apart from tumor volume and histologic grade, separate these "good" and "bad" tumors.

While it is impossible to predict the course that *microscopic* prostate cancers will follow, there are clear differences in survival and morbidity of the various *clinical* stages of the disease.¹⁷ These differences in outcome provide the basis for our efforts at early detection of this prevalent condition. Definitive treatment of early detected tumors has a well-docu-

monoclonal antibody radioimmunoassay of PSA (Hybritech) gives values between 0.0 and 4.0 ng/mL. When PSA values are higher than 4.0 ng/mL, there is a progressive increase in the rates at which prostate biopsy is positive for cancer, paralleling the rising PSA values. Extensive comparison of digital rectal examination (DRE), PSA, and transrectal ultrasound-guided biopsies have been published.¹⁹ Determination of PSA more than doubles the detection rate for prostatic malignancy when compared to DRE alone (2.0% compared to 0.5%). Prostatic ultrasound, although initially thought to be a reasonable screening tool, is expensive,

inconvenient, and has poor sensitivity and specificity for malignancy. The use of prostate ultrasound should be more appropriately reserved to guide biopsy of the gland. Careful imaging and accurate biopsy of multiple areas of the prostate allows for comprehensive tissue sampling in men with suspiciously elevated PSA values or obviously palpable prostate nodules or irregularities. The combination of an abnormal PSA value and a palpable prostate abnormality has a positive predictive value of nearly 80%.¹⁹

Digital Rectal Exam

Properly performed rectal exams carried out with consistency by the same examiner offer a means for comparison of annual prostate evaluations. These exams are best performed with the patient erect. The patient's hands are placed on the knees, and the patient is requested to bend the knees slightly. The examiner prompts a valsalva or bearing-down action from the patient to reduce discomfort, and the anal sphincter is parted with the examining finger.

The prostate normally is easily palpable with borders defining the apex, base, and lateral margins. The seminal vesicles are not normally palpable. In benign enlargement, the base of the gland may not be palpable. Nodules of firm tissue are suspicious for malignancy and

should be biopsied either by digitally directed or ultrasound-guided techniques. Discrepancies in consistency of the gland are described as irregularities rather than nodules. Deviations from the normal prostate may be secondary to malignancy, nodular hyperplasia, prostatic infarct, or granulomatous prostatitis. When PSA elevation accompanies such findings, malignancy is the prime consideration.

Referral and Treatment

Current strategies for prostate cancer detection use annual DRE and PSA measurement by the primary care provider as basic approaches. Abnormalities of either test should lead to referral for possible transrectal ultrasound-guided biopsy by radiologists or urologists trained in these techniques. The presence of genitourinary symptoms (voiding difficulty, hematuria, urine infection) makes urological evaluation prudent. Proper counseling on the extent of disease, treatment options, and expected outcomes can be provided by urology, radiation oncology, and medical oncology specialists.

Conclusion

The incidence of prostate cancer is increasing nationwide—and North Carolina is no exception. Currently, prostate

cancer is widespread throughout the state and is a special problem for blacks, where the mortality rate is double that for whites.

This "silent killer," once considered a taboo subject, is now receiving attention from both the government and the media. Prostate cancer may be the "male cancer of the 90s," forecasted to receive attention similar to that given to breast cancer during the past two decades. The first step in handling this disease, however, is to grasp the true magnitude of the problem—a step that begins with appropriate education and screening. □

Authors' Notes: *Prostate Cancer Awareness Weeks are September 27-October 11, 1992. Table 2, right, lists practices and centers that are holding free clinics and screening during this period. Contact these facilities for details.*

For further information regarding clinical trials for prostate cancer, Physician's Data Query (PDQ) searches, speaker's kits, patient information or referral, please call:

*Cancer Information Service
of the Carolinas
1-800-4-CANCER*

*Program of the National
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Table 2. Practices and centers participating in Prostate Cancer Awareness Weeks*—September 27 through October 11

Territory	Contact	City	Screening Site
Southwest	Paul R. Pastorini, M.D. & Associates Asheboro Urology Association Daljit Caberwal, M.D. Prithipa S. Hanspal, M.D. St. Joseph's Hospital Timothy Gajewski, M.D. & Associates	Albermarle Asheboro Asheboro Asheville Charlotte	Stanley Memorial Hospital Randolph Hospital Randolph Hospital St. Joseph's Hospital Mercy Hospital South, Presbyterian Hospital, University Hospital Carolinas Medical Center at practice Cabarrus Memorial Hospital Gaston Memorial Hospital Union Memorial Hospital Union Memorial Hospital Lake Norman Regional Medical Center at practice Rutherford Hospital Cleveland Memorial Hosp. Cleveland Memorial Hosp.
	Herman Godwin, Jr., M.D. Chris Teigland, M.D. Cabarrus Memorial Hospital Gaston Urological Associates Thomas Leitner, M.D. Richard Sowden, M.D. Clifford Kass, M.D.	Charlotte Charlotte Concord Gastonia Monroe Monroe Mooresville	
	Hazem El-Droubi, M.D. Stuart Powell, M.D. Cleveland Urologic Surgery Sherman Blackley, M.D. & Associates	Rockingham Rutherford Shelby Shelby	
Eastern	Betsy Johnson Memorial Hospital Cape Fear Valley Medical Center	Dunn Fayetteville	Betsy Johnson Mem. Hosp. Cape Fear Valley Medical Center
	Edward Janlesko, M.D. Lenoir Memorial Hospital Robert Garrison, M.D. John Lasater, M.D.	Greenville Kinston Morehead City New Bern	University Hosp. (Pitt County) Lenoir Memorial Hospital Carteret General Hospital Craven Regional Medical Center
	Samuel Storch, M.D. Johnston Memorial Hospital New Hanover Regional Hospital	Pinehurst Smithfield Wilmington	Moore Regional Hospital Johnston Memorial Hospital Martin Luther King Center
Central	Burlington Urological Associates Cary Urology	Burlington Cary	Burlington Urological Assoc. Eastern Wake Hospital, Western Wake Hospital, Southern Wake Hospital
	Central Medical Park Urology	Durham	Durham Co. Regional Hosp., Person Co. Memorial Hosp.
	Duke University Medical Center Sanford Surgical Clinic	Durham Sanford	Duke University Medical Ctr. Sanford Surgical Clinic
Northwest	Toya Brambul Martha Boschen	Boone Greensboro	Watauga County Hospital Wesley Long Community Hospital
	Robert Evans, M.D. Camille Townsend A. Donna Hickman Shanda Scal	Greensboro Greensboro Hickory Hickory	Moses Cone Mem. Hosp. Southeast Community Ctr. Catawba Memorial Hospital Frye Regional Medical Center
	Charles Rowe, M.D. Bob Grajewski, M.D. Jimmy Hart, III, M.D.	High Point Statesville Winston-Salem	High Point Surgical Center Statesville Medical Group Medical Park Hospital, Reynolds Health Center

*Prostate Cancer Awareness Weeks are sponsored by Schering Laboratories in conjunction with the Prostate Cancer Center Education Council.

REMEMBER
1975?

JANUARY 1 H.R. HALDEMANN, JOHN C. MITCHELL AND JOHN D. EHRLICHMAN, FORMER TOP AIDES OF PRESIDENT RICHARD NIXON, ARE CONVICTED OF CONSPIRACY TO OBSTRUCT JUSTICE IN THE WATERGATE CASE. **FEBRUARY 11** MARGARET THATCHER IS ELECTED LEADER OF THE CONSERVATIVE PARTY, BECOMING THE FIRST WOMAN TO HEAD A BRITISH POLITICAL PARTY. **APRIL 30** THE SOUTH VIETNAMESE GOVERNMENT SURRENDERS TO THE COMMUNISTS, ENDING THE WAR IN VIETNAM. ♦ **SEPTEMBER 29** THE MALPRACTICE SITUATION IN NORTH CAROLINA REACHES A CRISIS AFTER THE LAST COMMERCIAL INSURANCE COMPANY ANNOUNCES IT WILL NO LONGER PROVIDE MALPRACTICE COVERAGE IN THE STATE. ♦ **OCTOBER 1** IN MANILA, MUHAMMED ALI DEFEATS JOE FRAZIER IN THE FIFTEENTH ROUND TO RETAIN THE WORLD HEAVY-WEIGHT BOXING TITLE. ♦ **OCTOBER 23** NORTH CAROLINA PHYSICIANS CREATE A MUTUAL INSURANCE COMPANY TO ASSURE A STABLE, FAIR PROFESSIONAL LIABILITY MARKET. ♦ THE YEAR'S TOP FILMS INCLUDE *JAWS*, *ONE FLEW OVER THE CUCKOO'S NEST*, AND *NASHVILLE*.

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Why Does the Injured Drunk Driver Escape Arrest and Conviction?

A Case Presentation and Discussion by
Health Care and Law Enforcement Professionals

Thomas B. Cole, M.D., M.P.H., and Michael J. Patetta, M.A.

Serious injury protects the drunk driver from prosecution and conviction for driving drunk.¹ This escape from liability occurs despite the fact that almost half of all traffic fatalities are attributable to alcohol.² Consequently, the drunk driver who is injured may resume driving as soon as he is physically able to do so, thereby becoming a renewed threat to himself and others.³

On the other hand, a conviction for driving while impaired (DWI) results in loss of the driving privilege, reducing exposure of other drivers to a public health hazard. A DWI conviction may also stimulate the drunk driver to seek treatment for alcoholism. Unless they are prosecuted, even seriously injured drunk drivers are seldom referred for alcoholism counseling or treatment.⁴

To explore the reasons for this continuing cycle of impairment and injury, a panel of experts from the fields of health care and law enforcement was convened on October 30, 1991, during the Third Annual North Carolina Conference on Injury Control. The panel considered the hypothetical case of an alcohol-related motor vehicle crash in which a passenger was killed.⁵ We present here an edited transcript from that conference.

Moderator: Isaac T. Avery III, Special Deputy Attorney General, North Carolina Department of Justice
Panelists: Alfred R. Hansen M.D., Ph.D., Associate Professor, Department of Emergency Medicine and the Highway Safety Research Center, University of North Carolina at Chapel Hill;
C.E. Pearce, Operations Lieutenant, Troop C, North Carolina State Highway Patrol;
Michael Averbuch, Member, North Carolina Emergency Medical Services Advisory Council and former Vice President of Administration, Carolinas Medical Center; and
Carrie V. Carroll, Wake County Assistant District Attorney

Case Presentation

Two people are traveling in a car at excessive speed. Both have been drinking. The driver loses control of the car and hits a tree. The first people to arrive are civilian witnesses. Emergency medical services (EMS) personnel arrive before law enforcement does. One person has been thrown from the vehicle. He is dead. The other person is still in the vehicle, injured but alive.

Moderator: What should we advise the EMS personnel to do when they first get to the scene?

Dr. Hansen: Assess the scene, extricate the patients, start medical treatment, stabilize them, and prepare them for transport.

Moderator: Is it relevant that this is a crime scene? Should EMS be concerned about disturbing evidence?

Dr. Hansen: Their primary interest is taking care of the patient.

From Injury Control Section, NC Department of Environment, Health, and Natural Resources, P.O. Box 27687, Raleigh 27611.

Moderator:	So they should get the severely injured patient out of the vehicle?	Moderator:	Dr. Hansen, you now have this patient who has hit a tree, who probably had a head injury, and who is strapped to a gurney. What should you do as soon as he arrives at the hospital?
Dr. Hansen:	Oh, absolutely—as soon as possible.	Dr. Hansen:	We would suspect a serious injury in this case, and we would have alerted the whole trauma team. Usually we would do a primary survey to identify life-threatening injuries, and treat any problem that might kill the patient in the initial few minutes. We'd ensure that he was able to breathe and had plenty of intravenous fluids going in; we'd draw blood for routine tests, then go over him more carefully, get a series of x-rays, and consider special tests like CT scans.
Moderator:	We will assume that the EMS personnel put the injured man in the ambulance and leave. At this point the Highway Patrol arrives. Lieutenant Pearce, let's assume that it is 1:45 a.m., you're off at 2:00 a.m., and you get called for a vehicle collision with injury. You are told by civilians that there were two people in the crash. One is over in the trees dead and the other has been removed from the car and taken to the hospital by the ambulance. What are you going to do?	Moderator:	Assuming you detect an odor on the patient's breath would you order a blood alcohol level?
Lt. Pearce:	Well, our first objective is taking care of the injured. After that is done, we start collecting evidence, like beer cans and bottles, especially when you think the person had been drinking and driving. Then we try to find a witness. You would have to have a witness as to who was driving, otherwise we couldn't make a manslaughter case.	Dr. Hansen:	Well, in our institution, and in many others in this state, when a person appears seriously injured or has an impaired mental status, and we are not quite sure whether this is alcohol or head injury or both, we routinely obtain a blood alcohol test. I've surveyed my colleagues across the state and most of us are going to measure blood alcohol levels on someone like this patient. We are doing it for medical reasons, obviously, to help us understand why he is obtunded.
Moderator:	Will the fact that the EMS people have removed one of the victims from the vehicle affect your ability to do your job?	Moderator:	Now, Lt. Pearce has been out there collecting evidence at the scene. About how long will it take to complete your investigation and then get to the emergency department?
Lt. Pearce:	That depends on the circumstances. If somebody was pinned behind the wheel or strapped in behind the wheel it would definitely help our case. If he were removed and transferred, we try to find a witness and ask who was driving.	Lt. Pearce:	About one hour.
Moderator:	Meanwhile, the injured victim has been taken to a hospital emergency department. Mr. Averbuch, should the doctors start treating him or do they need to get consent first?	Moderator:	So you arrive at the emergency department about an hour after the patient. What would you do when you got there?
Mr. Averbuch:	The physicians and nurses are going to start treating him if there is no time for consent forms to be signed.	Lt. Pearce:	When I arrive at the emergency department, I would try to contact the emergency department nurse or doctor, which may be difficult to do because in all likelihood at that time they are treating the patient. It might be 30 to 45 minutes before I had access to this patient to form an opinion about whether or not the patient had been drinking.
Moderator:	Are they authorized to amputate a man's leg without asking him whether he wants it cut off or not?	Moderator:	Let's assume the EMS personnel indicated that this patient was the driver. Dr. Hansen,
Mr. Averbuch:	You always try to get a form of consent, but you don't withhold a procedure where delay may cause loss of life, limb, or permanent disability.		

would you allow this patrolman to walk into the treatment room to smell the patient's breath?

Dr. Hansen: We try to give access to the patient as soon as possible, but we may be busy with a patient like this for quite a while. Besides our assessment in the emergency department, the patient may be relatively inaccessible in the radiology department as well.

Moderator: Lt. Pearce, do you get that level of cooperation throughout your service with the state?

Lt. Pearce: I have had five duty stations and haven't experienced a problem being allowed access to injured patients. You have to know when you can ask to see the patient. You can't just walk in while the patient is being treated. I always get permission first.

Moderator: Dr. Hansen, you get the blood alcohol test and it registers 0.12, which is above the limit in North Carolina for conviction of driving while impaired (DWI). Would you share this information with the law enforcement officer so that he can do his job?

Dr. Hansen: I can't do that. I believe it would be a breach of the privileged physician-patient communication for me to share confidential medical information with law enforcement personnel, regardless of how I may feel about the issue personally.

Moderator: So even though you have substantial evidence in a homicide case, you're going to let this drunk driver walk free because of some legal technicalities?

Dr. Hansen: A number of us feel very strongly about this, but the law is clear. The sanctity of the physician-patient relationship is foremost unless the law is changed. If I were to release blood alcohol information that was obtained for medical diagnostic purposes, I might be liable for a breach of confidentiality suit.

Moderator: Well, let's say that the policeman finds out from someone that this person did have a blood alcohol concentration in excess of the legal limit or otherwise suspects him to be impaired. Lt. Pearce, how would you proceed?

Lt. Pearce: I would ask the patient to submit to another blood alcohol test, one to be used as evidence in court.

Moderator: Can you do that anytime you want to?

Lt. Pearce: If I have enough evidence to charge a man with driving while impaired I can.

Moderator: What if he refuses?

Lt. Pearce: Well, there is another way. I could get a search warrant and serve it on him. Then I would have to ask someone in the hospital to draw the blood.

Moderator: Let's assume that Lt. Pearce gets his search warrant. Mr. Averbuch, here is an officer with a search warrant wanting someone in the hospital to take this patient's blood. So what do you do?

Mr. Averbuch: We would want to cooperate, but often institutions are asked to do things without basic legal protection; I personally think appropriate legislation would make this problem much easier. If a court order were served and if I were the administrator on call, I would authorize emergency department staff to take the blood. However, hospital personnel in no way could restrain the patient. The highway patrol would have to restrain the patient.

Moderator: Let's assume that the police sample is .09. As we know, the legal limit is .10. So the officer brings the following information to the district attorney: a dead body, witnesses who put the patient behind the wheel of the car, and blood alcohol of .09 drawn three hours after the crash. With that kind of evidence, what kind of charges would the district attorney's office anticipate?

Ms. Carroll: Basically, we've got several options. We can charge him with felony death by vehicle, which is someone driving while impaired and causing a death to another person; manslaughter, which involves negligence; or second-degree murder. Of course the last two are more difficult to prove in court.

Moderator: What if Lt. Pearce told you that the hospital has a standing operating procedure to test blood for alcohol and that the police blood

alcohol of .09 was taken three hours after the one taken by the hospital. Would you try to obtain those hospital records?

Ms. Carroll: We certainly would. We're going to have a lot of problems unless we can get the higher reading.

Moderator: What legal process are you going to use?

Ms. Carroll: We would subpoena all the hospital records and personnel involved in treating the patient.

Moderator: Why can't you just use the hospital records? Why do you have to have all the personnel?

Ms. Carroll: For one thing we have a chain of custody problem.

Moderator: What do you mean by the "chain of custody?"

Ms. Carroll: Well, suppose we are dealing with the blood alcohol test done by Lt. Pearce; the chain consists of the person who drew the blood, the trooper who took the blood sample to the State Bureau of Investigation (SBI) for analysis, a chemical analyst advising the person of all their rights, SBI personnel who took the blood from the trooper, and any people involved in testing the blood. I don't mean having every single person who performed a test; but the more people in the chain we have available for court, the stronger our case will be and greater weight will be given to us.

Moderator: Mr. Averbuch, have you got the resources to have five or six members of your staff sitting at the Wake County Courthouse waiting on this trial for a day or two? Are you going to cooperate with the district attorney's office or say that your staff are not available?

Mr. Averbuch: Obviously they would have to be available if subpoenaed. But this is an instance where good medical records may make it unnecessary for personnel to appear in court. Often courts will accept the custodian of medical records in lieu of medical staff.

Moderator: Well, let me ask you, Ms. Carroll, would you rather have a custodian of records trying to

read the scribbling of a nurse or doctor to convince a jury that the driver was drunk, or would you rather have a live witness who actually did the scribbling to testify?

Ms. Carroll: Medical records seem to be a lot more credible and a lot better evidence if we've got the person who actually made the notations and record there. It's not realistic to have every person there who made every notation, but the more people we have who were directly involved with the patient and who can testify directly as to what they did and why, the stronger case we're going to have.

Moderator: Dr. Hansen, with your busy schedule at the emergency department, would you want to go and sit in a courtroom waiting to testify about a patient that you treated 12 months ago?

Dr. Hansen: Obviously nobody's real excited about wasting time, but there's a surprising sense of need to address this social problem. I think most of us are willing to do it as necessary, particularly if you can make efficient use of our time. What everybody objects to is being called to court, sitting there all day, and being sent home without ever being called to the stand.

Moderator: Don't you think your physician-patient relationship will be affected if you help to convict your patient of drunk driving?

Dr. Hansen: Perhaps, but one could argue that we also have a clear-cut responsibility to society in cases like this. There is an analogy to child abuse and neglect cases, where a physician is mandated to report a problem to prevent further harm to helpless victims. Even if you take the broad view of your responsibility to the individual patient, that responsibility includes seeing him prevented from further drunk driving, even if that involves prosecution. In the long haul, we might be doing the patient the better service by getting treatment mandated than by letting him go to drive drunk again. That potentially harms not only society, but the patient as well.

Moderator: Ms. Carroll, why would you let a doctor sit for three or four hours and never let him testify?

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The use of MAO inhibitors or tricyclic antidepressants with hydrocodone preparations may increase the effect of either the antidepressant or hydrocodone. The concurrent use of anticholinergics with hydrocodone may produce paralytic ileus. **Usage in Pregnancy:** **Teratogenic Effects:** Pregnancy Category C. Hydrocodone has been shown to be teratogenic in hamsters when given in doses 700 times the human dose. There are no adequate and well-controlled studies in pregnant women. VICODIN/VICODIN ES Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Nonteratogenic effects:** Babies born to mothers who have been taking opioids regularly prior to delivery will be physically dependent. The withdrawal signs include irritability and excessive crying, tremors, hyperactive reflexes, increased respiratory rate, increased stools, sneezing, yawning, vomiting, and fever. **Labor and Delivery:** Administration of VICODIN/VICODIN ES Tablets to the mother shortly before delivery may result in some degree of respiratory depression in the newborn, especially if higher doses are used. **Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from VICODIN/VICODIN ES Tablets, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. **Pediatric Use:** Safety and effectiveness in children have not been established. **ADVERSE REACTIONS:** The most frequently observed adverse reactions include light-headedness, dizziness, sedation, nausea and vomiting. These effects seem to be more prominent in ambulatory than in nonambulatory patients and some of these adverse reactions may be alleviated if the patient lies down. Other adverse reactions include: **Central Nervous System:** Drowsiness, mental clouding, lethargy, impairment of mental and physical performance, anxiety, fear, dysphoria, psychic dependence and mood changes. **Gastrointestinal System:** The antemetic phenothiazines are useful in suppressing the nausea and vomiting which may occur (see above); however, some phenothiazine derivatives seem to be antianalgesic and to increase the amount of narcotic required to produce pain relief, while other phenothiazines reduce the amount of narcotic required to produce a given level of analgesia. Prolonged administration of VICODIN/VICODIN ES Tablets may produce constipation. **Genitourinary System:** Urteral spasm, spasm of vesical sphincters and urinary retention have been reported. **Respiratory Depression:** Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated. **DRUG ABUSE AND DEPENDENCE:** VICODIN/VICODIN ES Tablets are subject to the Federal Controlled Substance Act (Schedule III). 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Initial and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. **Hydrocodone Signs and Symptoms:** Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac rest and death may occur.

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Ms. Carroll: Well we would certainly try not to inconvenience him. We would try to time our trial so that he didn't have to sit through jury selection and charges and bench conference, but we can't tell how long each step of the trial is going to last.

Moderator: Back to our story. In court the defense lawyer explains to the prosecutor that the accused, the defendant, lost his brother in the collision. The defendant himself is permanently disabled and is rolled into the courtroom in a wheelchair. Now are we going to prosecute this person who disabled himself and killed his brother?

Ms. Carroll: To the fullest extent of the law.

Moderator: Well what are your chances of prevailing with such a sympathetic defendant who's lost his own brother and hurt himself for life?

Ms. Carroll: Well, somebody who is charged with a homicide of a family member is going to be a very sympathetic defendant to a lot of people. However, that is not going to stop us from prosecuting him with whatever charge we believe we have the evidence to prove. Drunk driving is not a victimless crime. It could be that this man had a prior DWI in which he just totaled his own car and didn't hurt anyone except himself. Now he's been so unlucky as to kill his own brother, but the question is who is going to be his next victim?

Moderator: Can you estimate the chances of the jury convicting an individual in this case?

Ms. Carroll: I would have to say, based on my experience and on what I have read about this type of case throughout North Carolina, that it would depend on what county you're in. Believe it or not, there is a wide disparity between different counties as to how judges and juries treat impaired driving offenders. Also it would depend on some of the factors at the scene: How reckless was the driving? Can we show malice to the jury? Did he just run off the side of the road and then swerve back over the center and have a freak accident where he killed this man or did he go through a stop light at 70 mph driving on the wrong side of the road for a quarter of a mile? We have to consider factors like that. I would have to

say, unfortunately, that we would have less than a 50% chance of convicting him of second-degree murder under the story we've described. There is a very active element of society involved in anti-drunk driving campaigns, but we also have a big group of people who view drunk driving as something that, but for the grace of God, could happen to them. Unfortunately, no matter how carefully one picks a jury, we have some people who view drunk driving that way.

Moderator: What about you, Lt. Pearce?

Lt. Pearce: I would consider this a weak case because of the sympathy thing. In the 6 to 12 months before you could get him to trial the circumstances would be forgotten.

Discussion

Audience: What is the level of suspicion you have to have to request the driver to submit to a blood alcohol test?

Moderator: First of all you have to have probable cause to believe the person is guilty of driving while impaired.

Audience: Can the probable cause be established by statistics showing that 90% of the young drivers at that hour of the night or day are impaired when they have a crash? Isn't that enough?

Moderator: Possibly, but we would have to have the district attorney educated on the statistics and somehow prove those statistics in court. A much better law enforcement technique is to go into the emergency department and attempt to determine whether the person has been drinking. When you try to introduce the blood alcohol, the judge won't allow the results as evidence unless you have the officer testify that he found alcohol in the car or odor of alcohol on the driver's breath.

Audience: How will you get the blood alcohol records of the hospital admitted into evidence in a DWI case?

- Moderator:** This is a two-step procedure. First, you subpoena the records and have the judge determine that the physician-patient relationship should be waived in the interest of justice. Then it can be submitted as a business record. Because of time and effort it usually isn't subpoenaed in the normal DWI case except where there is a homicide. If there is a homicide, hospital records are quite routinely used in North Carolina when there is no law enforcement officer's alcohol test.
- Audience:** Is it appropriate for a physician to tell a law enforcement officer the extent of an individual's injuries and, if so, why shouldn't the physician also tell the law enforcement officer that he suspects this patient is a drunk driver?
- Dr. Hansen:** We are entitled to relay information about the general condition of a patient, usually through the public affairs office of the hospital. I believe I can tell the officer that "the patient is critically ill, and if you want to see him, do it now." But it would be both unethical and foolish for me to overtly suggest that the patient is inebriated.
- Mr. Averbuch:** Under current laws there is an obligation for physicians to report sexually transmitted diseases and child abuse and, in those instances, health providers are granted immunity. In my mind, we should change our laws so that health care providers, if requested by law enforcement officials, could give their opinion as to the mental status and intoxication of their patients.
- Audience:** Why not have a mandatory blood test for alcohol every time someone comes into an emergency room?
- Dr. Hansen:** Currently, the test must be medically justifiable. Some patients will ask why you are drawing blood and will want to know if we really need the information. Some will refuse to have it done, probably because they don't want incriminating evidence collected. If I don't absolutely have to have blood alcohol data for medical reasons, then it is hard to justify the test and the charge to the patient. Of course, if the patient is confused, lethargic, or unconscious, I can justify the test on medical grounds, since it helps shed some light on the altered mental status.
- Audience:** Why do we have such a problem convicting drunk drivers when injury is less of a problem?
- Ms. Carroll:** I wish I knew. Judges are aware of the law but some of them are not enforcing the law. I think judges need to be better educated about victims in drunk driving cases because apparently a lot of them view it as a victimless crime. □

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Blood Alcohol Concentration In Motor Vehicle Crash Victims

A Survey of North Carolina Emergency Physician Attitudes and Utilization Patterns

Cherri Hobgood Campbell, M.D., and Alfred R. Hansen, M.D., Ph.D.

Here are the facts:

1. Motor vehicle crashes are the leading cause of death in Americans aged 6 to 34 years.¹
2. A driver with a blood alcohol concentration of 0.05 g/dL is twice as likely to be involved in a fatal accident as a non-drinking driver.²
3. Driving after drinking is often not a sporadic behavior. Between 20% to 33% of drivers arrested for driving while intoxicated are subsequently arrested again on the same charge.³
4. According to Soderstrom et al, drunken driving signals an underlying alcohol abuse disorder.⁴ Indeed, it is reasonable to conclude that any alcohol use leading to injury should be considered a symptom of alcoholism.^{3,5}

Since intoxicated patients involved in a motor vehicle crash often present first to emergency physicians, these physicians are in a logical position to determine the blood alcohol levels of motor vehicle crash victims. This information would further public health goals by detecting alcohol disorder and documenting the need for treatment and rehabilitation of individuals but might also deter drunk driving by supporting prosecution of drunk driver statutes. We sought to determine what currently motivates emergency physicians to measure blood alcohol concentration in motor vehicle crash victims and to delineate factors that might change their practice patterns.

Methods

We surveyed all 374 active and resident members of the North Carolina College of Emergency Physicians (ACEP) with a

brief, anonymous, self-administered questionnaire concerning routine patterns of blood alcohol testing. We also asked the reasons why they did or did not measure blood alcohol as well as their thoughts as to which factors would stimulate more testing. Finally, information regarding the nature of the responding physicians' practice was requested. Data were compiled and the frequency of responses for each variable determined. The distribution of discrete variables was compared using the chi square analysis.

Results

The adjusted survey response was 57% (214/374). Of the 214 respondents, 92% practice emergency medicine full time; 74% practice in only one hospital; and 42% designated their practice as academic.

When asked "Do you routinely measure blood alcohol concentration data on motor vehicle crash victims?" 58% of respondents indicated that they test more than half of such patients. Most indicated they test approximately 50% to 75% of victims. Only 6% of physicians tested less than 10% of the time. There was no significant ($p < 0.05$) difference between the frequency with which blood alcohol concentration was measured in drivers and non-drivers (Figure 1, next page).

Nearly 50% of respondents determine blood alcohol concentration by protocol for all trauma victims (Table 1, next page). Of physicians currently ordering measurement of blood alcohol concentration routinely in drivers, 29% do so as documentation for law enforcement purposes. Factors that tended to increase the frequency of blood alcohol testing, independent of whether the crash victim was a driver, include: the presence of altered mental status in the patient (80%); the suspicion of intoxication (64%); and presence of serious injury (59%). There were no significant differences in the reasons for testing drivers versus non-driver victims of motor vehicle accidents.

From the Department of Emergency Medicine and the University of North Carolina Highway Safety Research Center, CB #7594, Chapel Hill 27599-7594.

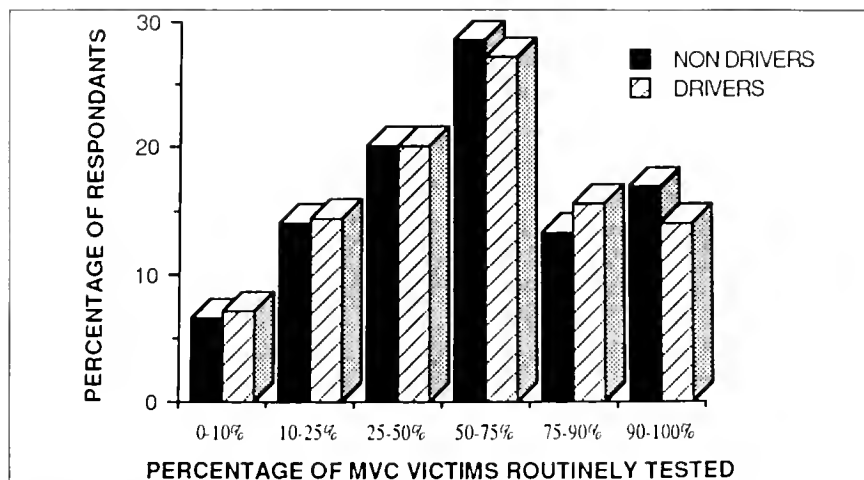


Figure 1: Frequency of measuring blood alcohol concentration in drivers and non-drivers involved in motor vehicle crashes.

There were no significant differences in ways in which full-time emergency physicians ordered the testing of blood alcohol concentration except that full-time academic emergency medicine physicians were one third more likely than full-time non-academic physicians to use a trauma protocol that specified measuring blood alcohol concentration in crash victims.

Only 7% of responding physicians said that they determine blood alcohol concentration in less than 10% of crash victims. The most frequent reason cited by these physicians for not obtaining the test was a "lack of clinical utility" for either drivers (51%) or non-drivers (69%); neither "cost" nor availability of the test was an important consideration in their decision. A sense of "conflict with their role as patient advocate" or a "reluctance to become involved in legal proceedings" was cited by 15% of physicians as factors that lessen the frequency with which they order blood alcohol levels in either drivers or non-drivers.

Whether or not they actually measure blood alcohol concentration, most physicians document clinical clues of alcohol impairment in motor vehicle crash victims. A majority document such findings in at least 75% of cases and many document clinical clues 90% to 100% of the time (Figure 2, opposite). Eighty percent of the physician respondents felt that measuring

blood alcohol concentrations in motor vehicle trauma victims could help identify problem drinking or alcoholism.

Several factors were identified as facilitating more regular blood alcohol testing (Table 2, opposite). More than half the respondents indicated that they would test more frequently if there were no risk of litigation from ordering blood alcohol measurements in patients who have questionable clinical indications. Respondents said that they would be more likely to obtain blood alcohol data if they felt the information would assist in the enforcement of impaired driving statutes or in research. Finally, the availability of a rapid and simple test of blood alcohol would also increase documentation.

Discussion

Each year 50,000 Americans die in motor vehicle accidents, more than half of which involve alcohol.¹ In North Carolina 35,000 occupants of vehicles (including a substantial number of teenagers) are involved in alcohol-related crashes, and 15,618 of these occupants are injured. In fact, between 49% and 66% of 15- to 24-year-olds involved in fatal crashes are intoxicated.⁷ Maull et al, in a prospective study of alcohol-impaired drivers,⁸ demonstrated that major injury actually protected drivers from arrest and prosecution for driving under the influence (see accompanying article on page 453. This "protection" from prosecution was confirmed by Colquitt et al who also noted that these injured drivers were rarely referred for professional counseling or treatment of their drinking problem.⁹ These reports illustrate the tragic consequences of drinking and driving and highlight the fact that neither the drunk driver nor the population at large are well served by current medical and legal practices.

The emergency department is the logical place to document the relationship between an individual's alcohol use and involvement in motor vehicle crashes. Simel and Feussner have previously surveyed emergency physicians in North Carolina to determine their use of blood alcohol data in a clinical scenario of minor injury.¹⁰ They found that emergency physicians were not inclined to request a quantitative blood alcohol concentration in a situation that did not include alteration of mental status, head injury, or obvious impairment. Our survey, which focused directly on the question of documenting alcohol levels in motor vehicle crash victims, yielded much more frequent positive responses. Of the physicians we surveyed, most routinely document clinical clues to alcohol use, and a substantial number routinely obtain blood alcohol levels in crash victims whether the patient was a driver or not. Most of North Carolina's emergency physicians also recognize that trauma, in associa-

Table 1. Responding physicians' rationale for obtaining blood alcohol concentration in drivers

Protocol for all trauma victims	48%
Altered mental status	80%
Confirm clinical suspicion of intoxication	64%
Serious injury	59%
Documentation for law enforcement	29%

tion with alcohol use, is a strong indicator of an alcohol abuse disorder.

Although the great majority of North Carolina emergency physicians feel that assisting in the identification and removal of the drinking driver from the highways is a part of good medical practice, some remain concerned regarding the legal liability involved in obtaining blood alcohol data without either a clear clinical rationale or an informed consent from the patient. Since 1985 the North Carolina Medical Society has supported legislation in the North Carolina General Assembly that would render physicians immune from legal liability for reporting to the Division of Motor Vehicles any driver whom they feel to be impaired. Some authorities have even suggested that reporting alcohol impairment should not only be permitted but required.⁹ Because denial is such a prominent aspect of alcoholism, reporting should be viewed as an act in the patient's interest and mandated in a manner similar to the reporting of child abuse. National survey data suggest a consensus of ACEP members feel "patients treated for injuries sustained as a consequence of alcohol-impaired driving should be reported to the authorities."¹¹

Although previous work in North Carolina suggests that the clinical use of quantitative blood alcohol concentration data will demand more attention to discharge instructions and may actually increase the physician's liability to civil suit if not taken into account in arranging the patient's disposition,^{12,13} our survey indicated a high level of social concern and a willingness to become involved in the diagnosis of problem drinking. We believe that public policy support and protection from litigation would encourage North Carolina emergency physicians to become more active in measuring blood alcohol concentrations. Involvement of the emergency physician in a formal

manner would result in improved follow-up care and better treatment for potentially unrecognized alcohol abusers, would lead to more uniform prosecution, and would support the national health objective of decreasing the number of alcohol-related motor vehicle crashes. □

Acknowledgment: The authors thank the NC ACEP members for their support of this survey, as well as the UNC Injury Prevention Research Center for their help and encouragement.

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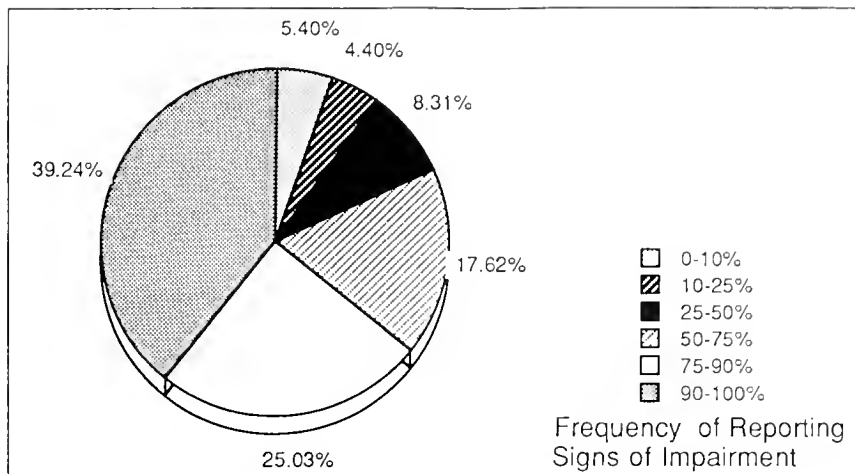


Figure 2: Percentage of cases in which physicians routinely document clinical clues to alcohol impairment in victims of motor vehicle crashes.

Table 2. Factors facilitating increased blood alcohol testing

Enhanced use of data for research purposes	58%
Eliminating risk of litigation	54%
Use of subpoenaed data to support prosecution	52%
Providing a rapid simple analysis method	43%

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Authors should submit papers prepared according to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (N Eng J Med 1991;324:424-8) with the following exceptions: 1) no abstract is needed for an article; 2) no running title is needed; and 3) measurements must be reported in metric units, but use of the International System of Units (SI) is optional.

To summarize major elements: All text (including Letters to the Editor) should be typed with one-inch margins, double-spaced, on one side of each sheet of paper. Title page should include addresses, and telephone and facsimile numbers of the corresponding author. Submit two copies or instead, and preferably, a cover letter and a 3 1/2- or 5 1/4-inch floppy computer disc containing the text written in MS DOS compatible format (WordPerfect, Microsoft Word, Displaywrite, or ASCII).

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Type figure legends, double-spaced, on a separate sheet of paper. Tables should be typed, double-spaced, one to a single sheet of paper. All tables must have titles and consecutive Arabic numbers.

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Fingerstick Detection of Hypoglycemia Can Prevent Dangerous Doses of Dextrose

John E. Gough, M.D.,¹ Jonathan L. Jones, M.D.,² and Herbert G. Garrison, III, M.D.³

Altered mental status spans a spectrum from mild confusion to obtundation and coma. Due to the large number of factors that can cause altered mental status, patients with this condition present a diagnostic challenge to health care providers. This challenge often falls to emergency department physicians and pre-hospital emergency response personnel.

The emergency management of the patient with altered mental status is the same as for all patients—to rapidly assess whether potentially life-threatening conditions are present and to direct interventions toward correcting those conditions. Once emergency measures have been instituted, a search for a specific diagnosis can be carried out.

Traditionally, the early emergency management of patients with an altered mental status has included the administration of naloxone, thiamine, and a 50% dextrose (D50) solution.¹ The argument

is that these medications pose little risk to the patient, but by treating common causes of altered mental status such as opiate overdose, Wernicke's encephalopathy, and hypoglycemia, they are helpful in both a diagnostic and therapeutic way.² Recently, however, the empiric administration of D50 has been questioned.³

Several authors have pointed out potential hazards of the empiric use of

an acceptable risk in order to treat potential hypoglycemia, which was viewed as more harmful.²

More recently attention has been directed toward the possibility of detrimental neurological effects of glucose administration in patients with cerebral ischemia.³ Animal studies have shown increased mortality, neurological morbidity, and histopathological damage in

animals with cerebral ischemia who have hyperglycemia or who received dextrose-containing solutions.⁴ Human studies have demonstrated poorer neurological outcomes in stroke patients and patients resuscitated from cardiac arrest who ex-

"The pathophysiology of the deleterious effect of glucose on ischemic brain tissue is unclear, but is possibly due to an increased accumulation of lactic acid produced by anaerobic glycolysis."⁵

D50.^{2,3} Complications of D50 infusion include skin necrosis following subcutaneous infiltration, worsening of hyperglycemia or hyperosmolality, and unpredictable alterations in serum potassium. However, since these complications are relatively uncommon, they were deemed

hibited higher glucose levels.⁵ The pathophysiology of the deleterious effect of glucose on ischemic brain tissue is unclear, but is possibly due to an increased accumulation of lactic acid produced by anaerobic glycolysis.⁵ In view of the fact that a large number of patients

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Table 1. Survey of utilization of fingerstick blood glucose determinations by North Carolina ALS rescue squads

	Number of squads	Number using FSBS	Number not using FSBS	Percent using FSBS
EMT-P	38	21	17	55.3
EMT-AI	15	11	4	73.3
Totals	53	32	21	60.4

who present to emergency departments or to pre-hospital emergency response teams with altered mental status are at risk for cerebral ischemia, the empiric use of D50 is being re-evaluated.

Several authors have recommended routine testing of blood glucose levels with fingerstick reagent strips in order to identify patients with hypoglycemia and restrict the administration of D50 to those patients.^{2,3} Reagent strips have been available for use in hospitals and homes for decades. Studies have shown their accuracy in predicting hypo- and hyperglycemia.⁶ More recently these reagent strips have been tested in the emergency department and pre-hospital setting with good results.⁷

The evaluation of blood glucose reagent strips in the pre-hospital setting has focused on their ability to accurately detect hypoglycemia. In this situation, determining the presence of hypoglycemia is more important than identifying a specific blood glucose level since hypoglycemia can be treated in the pre-hospital setting whereas hyperglycemia cannot. Studies have found reagent strips to have a sensitivity of 94% to 100% in predicting hypoglycemia as defined by a blood glucose level less than or equal to 61 mg/dL.^{6,7} Accurately detecting hypoglycemia can avoid unnecessary administration of glucose-containing solutions. Hogya, et al, found that less than one-fourth of the patients presenting with an altered men-

tal status were indeed hypoglycemic and therefore could be helped by D50 administration.⁷ Glucose reagent strips provide a quick, accurate, cost-effective means of screening blood glucose levels and can be safely used in the hospital and pre-hospital settings.^{6,7}

Reagent strips have been utilized by rescue squads for some time. However, we surveyed North Carolina paramedic (EMT-P) and advanced intermediate (EMT-AI) squads, the pre-hospital levels capable of administering intravenous D50, and found that only 60.4% of these advanced squads utilized fingerstick glucose determinations prior to administration of D50 (Table 1).

In view of the potential danger in giving dextrose-containing solutions such as D50 to patients who are at risk for cerebral ischemia, and the availability and accuracy of fingerstick reagent strips, we recommend that the empiric administration of D50 to patients with altered mental status be discontinued. Instead, we recommend routine use of fingerstick blood glucose determinations, to identify patients whose altered mental status is due to hypoglycemia and who therefore need supplemental glucose. This strategy will help those who need help and avoid unneeded and potentially dangerous treatment of those patients at risk for cerebral ischemia. □

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Carolina Physician's Bookshelf

Edward C. Halperin, M.D., Deputy Editor

Herbal and Magical Medicine—Traditional Healing Today, by Kirkland J, Mathews, HF, Sullivan CW II, and Baldwin K, (Eds.). Durham: Duke University Press, 1992.

Reviewed by Robert W. Prichard, M.D., Bowman Gray School of Medicine, Wake Forest University, Medical Center Boulevard, Winston-Salem 27157.

East Carolina University has a folklore archive whose size, regional focus, and contextual studies are among the largest in the country. Their faculty members, together with other experts in the field, have produced an excellent volume on a subject too often regarded lightly, or not at all, by modern physicians. Any reflective and experienced physician knows that "those beliefs and practices relating to disease that are the products of indigenous cultural development and are not explicitly derived from the conceptual framework of modern medicine" are very important in the practice of medicine. Not only are they important in the lives of his patients, but in the physician's own way of looking at disease.

From the Division of Radiation Oncology, Box 3085, Duke University Medical Center, Durham 27710.

No matter how sophisticated doctor or patient may consider themselves to be, folk beliefs and magic are not far beneath the surface, if submerged at all. This paperback puts the matter into perspective in an interesting and stimulating way.

The eastern part of Virginia and North Carolina are the focus of the book, enhancing its value for physicians in this area. The studies include blacks, whites, and Native Americans and have been done by experts of differing backgrounds who combine to better deal with the material. As one of these experts, David Hufford of Penn State says, primitive, i.e. nonscientific, medical practices are "a universal set of efforts to cope with illness in ways that go beyond—but do not necessarily conflict with—what modern medicine has to offer."

Of course, those folk beliefs may well conflict and this too may be easier to deal with if the physician knows the background of the beliefs. This collection provides an easy way to learn more about the very wide range of medical-related folklore that has been catalogued and analyzed. The aim is to reach not only anthropologists and folklorists but people in medicine and its related disciplines.

Hufford's chapter is based on his 18-year experience teaching at Penn State's medical school; it provides a solid background for what is to come in the book. In the next chapter, Blaustein encapsulates the chapters that follow and interconnects the themes of those chapters and of Hufford's, thereby giving useful perspective; he is a professor of sociology

and anthropology at East Tennessee and teaches at their medical school as well.

Two physicians have written chapters. Peter Lichstein is an ECU faculty member writing on "Rootwork from the Clinician's Perspective." "Parallels Between Magico-Religious Healing and Clinical Hypnosis Therapy" is the work of Robert Sammons, whose medical degree is from UNC; he now practices in Colorado. The other chapters deal with burn treatment, root doctors, and patients who use both MDs and root doctors, spiritual heart trouble, and herbal medicine of the Lumbees, childbirth education, and associated beliefs and the aesthetics involved in transmitting folk-medical beliefs. Each chapter contains good references and provides an excellent bibliography of the field.

For a weekend's reading a physician can hardly find a better book. Not only does it have direct application to medical practice, it stimulates one to recall the part folk medicine has played in one's private and professional life. And there are lots of little tidbits to toss into conversation for a long time to come. □

Books Briefly Noted

Essential Immunology, 6th Edition, by I. Roitt. Oxford: Blackwell Scientific Publications, 1988, ISBN 0-633-01994-9.

Fundamental Immunology, 2nd Edition, by W.E. Paul, (Ed.). New York: Raven Press, 1989, ISBN 0-88167-491-5.

Essential Medical Physiology, by Johnson, LP. (Ed.). New York: Raven Press, 1992, ISBN 0-88167-738-8.

Reviewed by Edward C. Halperin,
M.D., Box 3085, Duke University
Medical Center, Durham 27710.

From time to time I have these seizures when I think I am a medical student again. I am overcome with the uncontrollable urge to read basic science texts. I'm sure you've had the urge. "Now that I really understand what I need to know, I am going to go back and review my basic science text," you must say to yourself.

For most people, the urge passes without too much difficulty. For me, the urge only passes after I lay out a few hundred dollars for high-priced textbooks, attempt to read them, and get frustrated.

My attack of this fall/winter resulted in the purchase of three books: Roitt's *Essential Immunology*, Johnson's *Essential Medical Physiology*, and Paul's *Fundamental Immunology*. I'm not so sure that any of them are "essential" or "fundamental," since I seem to have made it this far in my career without knowing much of what was inside any of them. Nonetheless, I plowed ahead.

The book by Ivan Roitt is used as a medical school textbook. It is filled with straightforward diagrams that try to get the reader from point A to point Z without too much mystery. Unfortunately, when it comes to the immune system, this is no mean task. Nonetheless, even for idiots like me the book was successful.

Paul's book, *Fundamental Immunology*, is clearly not for idiots like me. It is a densely written and referenced textbook with everything anyone ever wanted to know about immunology for now and forever more. The book is intensively footnoted, printed in small type, and minute in detail. It can serve as a reference textbook for the aficionado.

Johnson's *Essential Medical Physiology* is a sprightly written, nicely printed medical school textbook. It is short on references, heavy on explanation, and nicely illustrated. It also won't make good bedtime reading. This is a book to come back to and read as the clinical problem, requiring a better knowledge of physiology, presents itself.

Johnson's or Paul's book will also serve nicely to prop-up the slide projector for a lecture. □



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Health Watch

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Health Issues of the Young

HEALTHY YOUTHS

Adolescence is a time of rapid physical and emotional change and a period of learning and experimentation. Attitudes and behaviors, developed during this time, that relate to diet, exercise, sexual practices, safety habits and tobacco and alcohol use may have health consequences that continue through adulthood.

The dominant preventable health problems of adolescents and young adults fall into two major categories: injuries and violence that kill and disable many before they reach age 25; and emerging lifestyles that affect their health many years later.

In this article we will take a look at some of these problems and explore ways to deal with them.

Sex

Sexual activity among teenagers poses special risks, such as unwanted pregnancy and sexually transmitted diseases, including HIV infection.

Pregnancy

Initiation of sexual activity at a young age is a primary risk factor for unintended pregnancy. Researchers say that more than one million young American women under the age of 20 become pregnant unintentionally, out-of-wedlock each year. Most have reasons, mistaken ones, for believing that it can't happen to them. Ignorance concerning how one gets pregnant and how to prevent it are the main contributors to this problem. These unplanned pregnancies often create problems for the young mother and child, threatening both their physical and their emotional health. Health risks to teenage mothers include: a higher death



rate from pregnancy complications, a greater chance of suffering from premature or prolonged labor and the likelihood of having babies with low birthweights—increasing the risk of these babies having health problems.

Sexually Transmitted Diseases

By age 21, approximately one in five young people has acquired a sexually transmitted disease. Because not all teenagers are sexually active, this amounts to a rate of at least 25 percent among those who are. Teenagers report that social pressure is the chief reason why their peers do not wait until they are older to have sexual intercourse.

Only one-third of teenagers who have had sexual intercourse say they use contraceptives all the time. Sexually active teenagers who have talked about sex, pregnancy, and contraception with their parents or who have a strong appreciation of the consequences if they or their partner becomes pregnant are most likely to use contraceptives consistently.

Parents are the first and most important educators of their children in matters related to sexual behavior. Children also learn about sexuality from other sources, their schools, their peers, and the mass media. Research consistently shows, however, that family support, family guidance and family structure have a significant effect on sexual activity. By the development of better parenting skills through self-study and parent skill classes and greater involvement in educational programs for their children, parents can fulfill better their responsibilities for teaching their children about sexuality.

Depression/Suicide

The teens are years of turmoil for just about everyone. There are new social roles, new relationships, body changes and decisions to be made about the future. So, when on top of these problems, a particularly hard challenge comes along such as parents' divorcing or doing poorly on a major college entrance exam, a teenager may begin to feel depressed and even wonder if life is worth living.

Depression is a very common illness, even among teenagers. Depressed people often experience feelings of hopelessness, low self-esteem and sadness. Because of the pressures of change that they are already experiencing, teenagers are especially susceptible to periods of depression. For most teens, periods of depression are short lived and do not substantially affect their lives. For others, however, their depression is severe and seemingly unending. Without help these teens may see suicide as a solution to the emotional pain and permanent unhappiness their depression is causing them.

According to recent studies, 10% of students now in high school have attempted suicide at some time in their lives. These teens are making serious cries for help. They have lost sight of who they are, feel hopeless about the direction of their lives and helpless to do anything about it. Many are feeling profound despair and probably have struggled with thoughts



of suicide for some time. They often provide clues to their intentions. It is important to know what these clues are and be cognizant of them when we are dealing with a depressed individual. Some of the things we can be aware of are:

- marked changes in personality, behavior, appearance
- poor self-image
- participation in new and self-destructive behaviors
- talk of death/dying
- signs of depression such as insomnia, apathy or noticeable weight loss/gain
- preparation for dying, such as giving away important and treasured objects
- apparent loneliness and isolation or withdrawing from others

If you think someone is suicidal there are a number of things you can do.

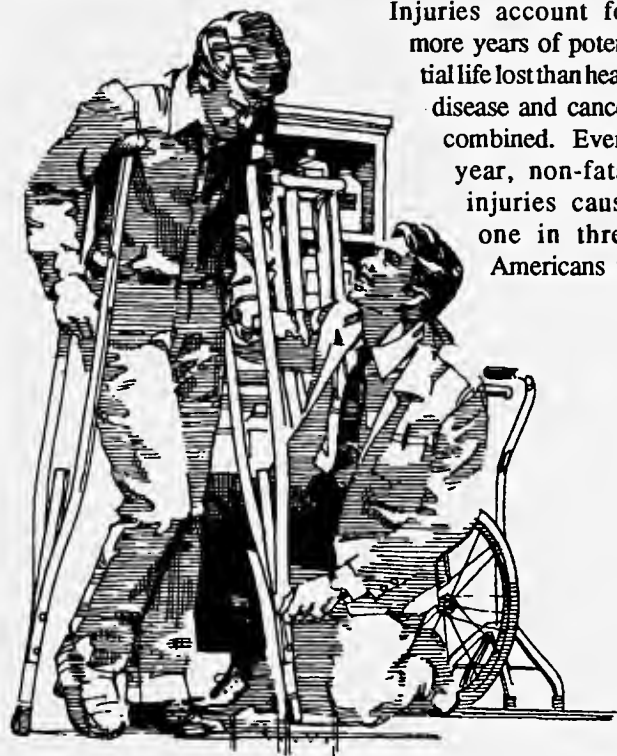
1. Do not ignore warning signs.
2. Find a time privately to let them know what clues you've observed and that you are concerned that they might be thinking of giving up on life.

3. Stay calm and simply listen. If you are right, they most likely will be relieved that someone noticed and cared.
4. Remember—you cannot make them choose to live. You are not responsible for their life, but you can give support and possibly insight into other choices.
5. Remind them that suicide is a permanent solution to a temporary problem.
6. Reassure them that many people think about suicide but never actually do it.
7. Be honest with them if you plan to call a family member or friend. Make the call in front of them so that they won't wonder what you're saying.
8. Ask them to agree to postpone the decision for a while; in return, offer to accompany them to find support or help.
9. Know the services available in your area, or contact someone who does.

Injury

Injuries are the leading cause of death and disability in children and young adults. They destroy the health, lives and livelihoods of millions of people, yet they receive scant attention, compared with diseases and other hazards. In North Carolina six out of every ten deaths of children 1 to 19 are accidental.

Injuries account for more years of potential life lost than heart disease and cancer combined. Every year, non-fatal injuries cause one in three Americans to



seek medical attention or render them unable to perform normal activities. About 40% of these injuries are said to be preventable. The key to prevention is putting safety first.

Among young children, the largest numbers of injury deaths are caused by motor-vehicle crashes, drowning and fire; pedestrian deaths constitute a major problem in urban areas. Especially high death rates among teenagers and young adults are associated with motor-vehicle crashes, firearms and drowning.

Motor-Vehicle Injuries

As both drivers and passengers, teenagers are disproportionately involved in motor-vehicle crashes, compared with people of other ages. Even though they drive less than older people (except those 70 and older), teenagers have very high numbers of motor-vehicle crashes and crash deaths. Let's look at some facts involving teenagers and motor-vehicle injuries.

- Teenagers comprised 10 percent of the U.S. population in 1991 and 14 percent of all motor-vehicle deaths.
- More than 40 percent of the deaths of 16-19 year olds from all causes in 1989 occurred from motor-vehicle crash injuries. These injuries comprised almost half (48 percent) of the deaths of females 16-19 years old.
- More than twice as many male teenagers as female teenagers are killed in motor-vehicle crashes.
- Twenty percent of all passengers who die in motor-vehicle crashes do so when a teenager is driving. Most teenage passenger deaths (63 percent) occur in crashes in which another teenager is driving.
- More than half (58 percent) of all teenage motor-vehicle deaths occur on weekends (Friday, Saturday and Sunday).
- About half of all teenage motor-vehicle deaths occur between 9 pm and 6 am.
- Motorcyclist deaths begin rising during the teenage years. Teenagers comprise 14 percent of all motorcyclist deaths.

What can be done to address this problem?

Legal/Technology

- Several states have enacted curfew laws that prohibit 16-year-olds from driving late at night and early in the morning (usually midnight to 5 am). One study involving four states with such laws showed that crashes involving 16-year-olds were reduced by 25 to 69 percent.

- Continued efforts to increase the use of seatbelts and other active restraints. This involves not only enforcement of laws requiring use of restraints but also more education about their life-saving and injury-preventing benefit.
- Support the incorporation of passive restraints such as air bags in all cars.

Parents

- Parents should provide their teenagers with plenty of supervised driving practice when they are learning to drive and even after they get their licenses.
- Parents should make every effort to enforce no-drinking-and-driving rules. If their teenage children do drink, despite the rules, parents should make sure there's a way for them to get home without driving.
- Parents should place restrictions on nighttime driving by their teenage children. ☐

Conclusion

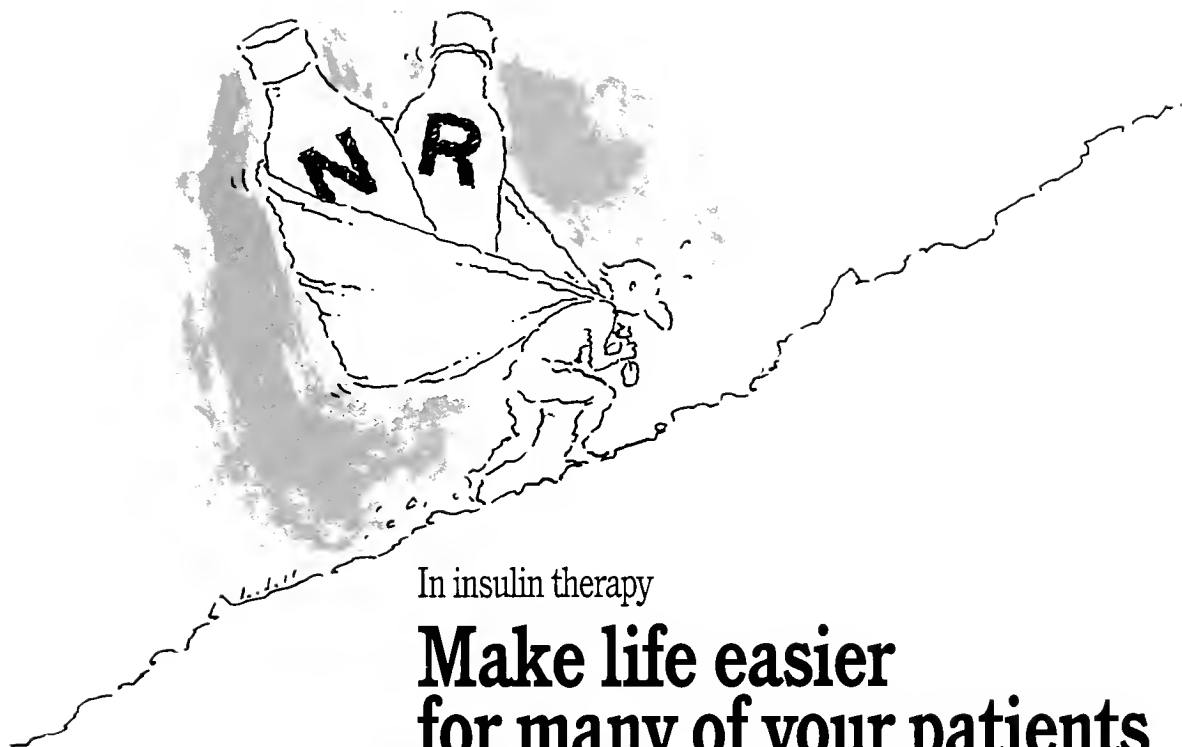
Adolescence is, needless to say, a critical period of development. One is no longer a child nor yet an adult. It is during adolescence that some persons adopt self-damaging behaviors that can threaten or shorten life. It is also a time when good examples and models can go a long way in influencing future behavior. The opportunity to contribute to the better health and safety of young people is one that we don't want to miss.

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Where Are We and How Did We Get Here?

Federal Regulation of the Office Laboratory

E. Rodney Hornbake, III, M.D., F.A.C.P.

Physician's office laboratories have been rounded up, tried, and sentenced to supervised probation. It was a case of mistaken identity and confusion of purpose by the sheriff.

The perpetrator of the crime was not even a doctor's office laboratory. It was an independent laboratory that failed to identify malignant cells on Pap smears. The victims were women who died as a result. The media told the story to a horrified public and the cry for justice was sounded. The jury was the Congress of the United States. The presiding judge was John Dingle, Chairman of the House Energy and Commerce Committee. The verdict was guilty of all charges including lack of quality control, use of improperly trained and inadequately supervised personnel, and maintaining uninspected and non-accredited facilities.

At least that is the way some people see it.

But regardless of one's point of view the result was Public Law 100-578, better known as the Clinical Laboratory Improvement Amendments of 1988 or simply as CLIA 88. This monumental piece of federal legislation brings the hand of government into every laboratory

that tests human specimens in the U.S. For physicians who test blood and urine in their offices it means registration fees, onerous paperwork, and surprise visits by federal inspectors. It may also mean sudden loss of the ability to perform these tests, criminal penalties, expulsion from the Medicare program, and large fines for any doctor who fails to pass muster or who violates the law.

This kind of story is not unique in the nation's annals. The writings of Upton Sinclair and his fellow muckrakers brought reforms to the meatpacking and pharmaceutical industries. Ralph Nader pointed out cars that were "unsafe at any speed." Water and air quality standards have come about as a result of widespread publicity about the public health. But doctors are used to being respected and trusted. We are "experts" after all. Who but one of us is able to judge what we do?

The answer these days seems to be just about everyone. Our reserves of trust are badly depleted. Judging from proposals before Congress and various state legislatures the public seems to be ready to regulate much of what we do. From the limiting of fees to the banning of certain types of referrals to "consumer" representatives on licensure boards, the profession is under a regulatory siege. One wonders who or what will be catapulted over the castle wall next.

How should we respond? How can

a noble and learned profession cope with what many perceived as assaults on our autonomy? Our response to laboratory regulation provides an object lesson in our struggle with this question.

The Path to Medical Laboratory Regulation

The story begins with the birth and development of the clinical laboratory early in this century. Physicians have come to rely more and more on the clinical laboratory. Now it is hard to imagine practice without one. The link between quality of patient care and accuracy of laboratory studies is immediately apparent. Quality assurance and proficiency testing are essential parts of laboratory medicine.

Shortly after the federal government began to pay for laboratory services through the Medicare program the need for laboratory regulation became clear. The massive amounts of federal funds available for laboratory studies created the potential for serious fraud and abuse, and Congress became concerned about value received for money spent. How could Congress assure that the funds it appropriated had purchased quality laboratory services? The first answer took the form of the Clinical Laboratory Improvement Amendments of 1967 (CLIA 67), which set personnel, proficiency

From P.O. Box 529, Vanceboro, NC 28586.

testing, and quality assurance standards for all labs involved in interstate testing. Physician's office laboratories were not included in CLIA 67.

During the next two decades advances in technology led many physicians to expand their laboratories beyond a simple microscope and centrifuge. Having the results of blood chemistry determinations, therapeutic drug levels, and other studies available at the time of an office visit unquestionably improved patient care. The new technology permitted this. The new technology also meant that physicians would assume a new role as laboratory manager. Many physicians responded enthusiastically to this new role. Few had received formal training in laboratory management, but most had obtained some laboratory experience while earning an undergraduate degree in the sciences. Equipment manufacturers assisted physicians by providing instruction in the use of equipment to the doctor and his staff.

In response to this expanded laboratory managerial role for doctors, physician organizations offered voluntary proficiency testing programs to their members. The American Society of Internal Medicine (ASIM) began its Medical Laboratory Evaluation program in 1973. The College of American Pathologists (CAP) marketed its proficiency testing programs to physicians, and later the American Academy of Family Physicians (AAFP) developed its program. In 1985 ASIM, CAP, and AAFP joined together to form the Commission on Office Laboratory Accreditation (COLA)—a voluntary agency whose purpose was to accredit office labs. The American Medical Association (AMA) later joined the COLA, and other organizations have applied for membership.

Congress also responded to the "regulatory vacuum" surrounding the physician office laboratory. In 1987 Congress opted for mandatory quality assurance by including in the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) a provision for regulation of office labs. OBRA 87 specifically required that "high-volume" office labs

meet the same standards as commercial laboratories. OBRA 87 left it to the Secretary of Health and Human Services to write the actual regulations, but Congress intended to regulate most office labs.

The Response of Medicine

By dropping this requirement into the OBRA legislation at the last minute Congress caught physician organizations off guard. Suddenly physicians were faced

"The American Society of Internal Medicine testified that regulations should provide for flexible personnel standards, recognize different levels of complexity in testing, and allow for accreditation by voluntary bodies like the Commission on Office Laboratory Accreditation."

with the prospect of having their office labs regulated out of existence. Thus in 1988, at public hearings held in response to the Pap smear scandal, the AMA and others gladly took the unexpected opportunity to testify on the regulation of physician office labs. Given the political climate, the best physicians could hope for was to get regulations they could live with. A roll back to the pre-1987 status quo was simply not an option. In fact by actually supporting CLIA 88, organized medicine placed itself in a strong position to negotiate with Congress for a law that would preserve the office lab. After all,

medicine already had a model program for assuring laboratory quality: COLA. ASIM testified that regulations should provide for flexible personnel standards, recognize different levels of complexity in testing, and allow for accreditation by voluntary bodies like COLA. All three points were included in the final version of the law. Without this input CLIA 88 would have put most office labs out of business.

Congress made known its will but in rather broad terms. The next step was the transition from federal law to regulation, and it was up to the Secretary of Health and Human Services to develop workable regulations. This task was assigned to the Health Care Financing Administration (HCFA). Consider the magnitude of the undertaking. There are an estimated 130,000 office labs in the country, ranging from the very simple to the very complex. They use hundreds of different instruments utilizing varying methodologies and produced by a host of manufacturers.

The regulations were released in June 1990. Under U.S. Administrative Law this first release is published in the *Federal Register* as a "Notice of Proposed Rule Making"—bureaucratic jargon meaning that interested parties have a period of time to comment on proposed regulations and that rule makers are required to take these comments into consideration. And comment we did. HCFA received 60,000 letters. (A record number of responses that was surpassed only by physicians' 95,000 comments on Medicare Physician Payment Reform in 1991.) This large volume protest gave evidence that the proposed rules were unworkable and would have forced most office labs to close.

In response to the avalanche of letters, Secretary of Health and Human Services Louis Sullivan ordered a complete revision of the regulations. He re-assigned the task from HCFA to the Centers for Disease Control (CDC). Sensitive to physician complaints, the CDC took several important steps, including the hiring of physician consultants such as physician members of the COLA board

Table 1. Waivered tests

1. Dipstick or tablet urinalysis for bilirubin, glucose, hemoglobin, ketone, leukocytes, nitrite, pH, protein, specific gravity, or urobilinogen.
2. Blood glucose using devices approved by the FDA for home use.
3. Ovulation tests (visual color tests for luteinizing hormone)
4. Urine pregnancy tests (visual color comparison method)
5. Spun microhematocrit
6. Hemoglobin by copper sulfate method (non-automated)
7. Fecal occult blood
8. Erythrocyte sedimentation rate (non-automated)

of directors. These consultants recognized the need to preserve patients' access to care and developed a list of tests critical to the operation of small rural hospitals. (Some CLIA 88 labs are not in physician offices.) The CDC also took steps to ensure that experienced physicians could continue to direct office labs. Finally, the CDC considered both the analytic and testing methodology in determining the complexity of the tests being regulated. This moved many tests from the highest complexity level to a more moderate level with resulting relaxation of personnel requirements for most office labs.

But on some points the CDC, largely in response to congressional pressure, refused to move. The list of tests exempted from regulation—the so-called waived tests—actually contracted with the second writing of the rules. The requirement for surprise inspections of office laboratories remained despite physicians' loud protests that this would disrupt the care of patients.

The CLIA 88 Regulations

What are the key elements of the final CLIA 88 regulations? Here are those of most importance to physicians.

1. There are three levels of laboratory test complexity (designated waived, moderate, and high) depending on the

menu of tests that a lab performs. The level of complexity determines the personnel requirements of the laboratory.

2. Laboratories performing only waived tests (Table 1) must register and pay a fee of \$100 every two years. They are otherwise exempt from regulation.
3. Laboratories performing tests of moderate and high complexity must meet the requirements listed in Table 2. The complexity classifications of 5,000 testing methodologies were published in the February 28, 1992, *Federal Register*. Another 10,000 are promised before September 1, 1992.

Table 2. Requirements for high and moderate complexity labs

1. High and moderate complexity labs must meet appropriate quality control and quality assurance standards.
2. High and moderate complexity labs must participate in an approved proficiency testing program by January 1, 1994.
3. High and moderate complexity labs must submit to biennial unannounced on-site inspections, the considerable cost of which must be paid by the laboratory.
4. Moderate complexity labs have limited restrictions on personnel. Most physicians currently directing a lab should be able to continue to do so.
5. High complexity laboratories have more stringent personnel requirements, but physicians with two years experience directing or supervising high complexity testing can continue to do so.

4. No laboratory will be sanctioned or closed until 1995 unless it poses an imminent threat to the public health.

What Should Doctors Do

How should physicians respond to these requirements? Here are several points to consider.

1. **Count the costs.** These new regulations will add about \$1 billion to the nation's laboratory bill. HCFA estimates the cost of regulation will add 25 cents to each test. For some office labs the cost will be many times higher. If, after careful analysis, you decide to close your laboratory, please share your decision and the analysis behind it with the North Carolina Medical Society (Deborah Nelson, NCMS, P.O. Box 27167, Raleigh, NC 27611). If your decision inconveniences your patients ask them to let their congressional representatives know.
2. **Analyze your testing menu.** It may be wise to drop a few tests if this would bring you into a lower complexity category. On the other hand, consider expanding your menu to offer other tests of the same complexity.
3. **Consider joining or forming a group practice.** Economies of scale may provide the only way for many labs to survive.

4. **Analyze your personnel needs.** Pay close attention not only to who is doing the tests now but to who will do the tests in the future. Your technician may qualify now based on experience ("grandfathering"), but after that person retires or moves on you may have to hire someone with formal training at much higher wages.
5. **Enroll in proficiency testing.** This is essential. Proficiency testing will help you find your problems now, before you can be sanctioned or your laboratory closed.
6. **Seek voluntary accreditation.** If you are already enrolled in proficiency testing consider advancement to the next level of excellence. COLA accreditation will let your patients and colleagues know that you have been certified as providing excellent laboratory services.

In addition, COLA will very likely be granted "deemed status" by HCFA. So if your lab is accredited by COLA you will not have to worry about federal inspectors.

Our Lessons

What have we learned? This large scale encounter between the profession and government was a learning opportunity. What if we had resisted laboratory regulation? It is quite clear that we would have ended up with unworkable regulations that would have forced the closure of most office labs. There are those who wanted just that. Hospitals and large commercial labs see Dr. Jones as a unwanted competitor. For instance, the American Society of Clinical Pathologists called our hard won concessions to access in the final regulations "a grave error."¹ And the American Society for Medical Technology said that certain provisions will "compromise the quality of laboratory care offered in this nation's 12,000 hospital and independent clinical labs and will have little impact on currently unregulated labs."

It is worthwhile to examine the CLIA 88 regulations from a longer view. As noted ethicist Albert Jonsen² has pointed out, high technology brings us ambiguities regarding two of the ancient cornerstones of medical ethics: competence and be-

neficence. The laboratory is a necessity for bringing to patients the benefits of modern science. But the community has expressed doubts about the competence of some laboratories. Moreover, the ancient tension between the profession of medicine practiced solely for the benefit of the patient and the business of medicine conducted for the mutual benefit of two parties has been heightened. Jonsen points out that this tension can never be entirely resolved; that it is heightened at times and lowered at others by changes in behavior and perception.

How can the profession and the community lower the level of tension and reduce the level of ambiguity? Regulation has been the choice in our society. CLIA 88 has reassured the community that office laboratories will be operated with high degrees of competence. The profession's input into the process of rule making has focused on the benefits of ready access to laboratory services and the need to pursue excellence. Although we must be businesspeople, in this encounter we have convinced the community that we are first and above all professionals. □

Where to Find Help

The following organizations offer proficiency testing for physician office laboratories:

American Academy of Family Physicians
AAFP-PT
8830 Ward Parkway
Kansas City, MO 64114
800/274-2237

American Society of Bioanalysts
205 West Levee
Brownsville, TX 78520
800/234-5315

American Society of Internal Medicine
Medical Laboratory Evaluation
2001 Pennsylvania Ave.
Washington, DC 20005
800/338-2746

College of American Pathologists
325 Waukegan Road
Northfield, IL 60093-2750
800/323-4040

For a detailed summary of CLIA 88 regulations order "CLIA 88 and Your Laboratory" from the American Society of Internal Medicine, P.O. Box 96013, Washington, DC 20090-6013. Cost is \$40 (\$25 for members). No phone orders accepted.

To apply for voluntary accreditation contact COLA:

Commission on Office Laboratory Accreditation
8701 Georgia Ave., Suite 610
Silver Spring, MD 20910
301/588-5882

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Shock and Prolonged Muscle Cramps After Intravenous Insulin Therapy

Andrew H. Meyer, M.D., and M. Sue Kirkman, M.D.

Fluid and electrolyte shifts are known to occur with insulin therapy and are occasionally the desired result of treatment, as when insulin is given for severe hyperkalemia. When physicians prescribe insulin for a more common indication, hyperglycemia, we may be surprised by unusual side effects that occur due to rapid movement of water and solutes between body compartments. We describe a dramatic case of the acute onset of shock and painful muscle cramping, along with a rapid decrease in serum potassium and glucose, in a patient who received intravenous insulin for asymptomatic hyperglycemia. After we made a patient feel considerably worse because we attempted to make his "numbers" look better, we felt the need to review some physiology to understand why a commonly prescribed therapy had such disastrous side effects for our patient.

Case Report

The patient is a 58-year-old African-American man with a 35-year history of type I diabetes mellitus that has been complicated by peripheral neuropathy, retinopathy, and chronic renal insufficiency. He has had numerous hospital admissions for diabetic ketoacidosis and has suffered many episodes of severe unheralded hypoglycemia. He presented to the medical clinic for a routine appointment with no active complaints. His blood pressure was 123/82 mm Hg, pulse was 92 per minute, and weight was 65 kilograms. After the clinic nurse found the patient's blood sugar by reflectance meter to be "HHH," she sent him to the laboratory for a Chem-7. Soon thereafter, a

laboratory technician called to report a "critical" glucose result of 670 mg/dL. The serum sodium was 131 mmol/L, serum potassium was 5.3 mmol/L, serum bicarbonate was 23 mmol/L, BUN was 89 mg/dL, and creatinine was 6.0 mg/dL.

Although the patient felt fine and his blood chemistries showed no evidence of acidosis, we felt compelled to treat the "critical" glucose value. We rejected our initial plan to give the patient subcutaneous insulin alone as likely to be too delayed in effect (after all, this was an afternoon clinic for us, and the patient's ride was waiting). We gave the patient 10 units of regular insulin subcutaneously along with 10 units of regular insulin intravenously.

Approximately one hour later, as the nurse was rechecking his capillary blood sugar (247 mg/dL), the patient suddenly developed severe muscle cramps in his calves, sides, and back. He slumped over and was found to have a blood pressure of 60/49 mm Hg and a pulse of 110 per minute. He was taken to the emergency room, where his state of shock was manifested by confusion, continued hypotension, and our inability to obtain peripheral intravenous access. We infused 500 cc of normal saline through a central line, which produced a rapid return of his baseline blood pressure and state of alertness. However, the patient continued to have frequent palpable and obviously painful cramps of the muscles of his legs, buttocks, and trunk.

Meanwhile, results of a second Chem-7, drawn 90 minutes after the insulin injection and just before the normal saline bolus, returned. The blood glucose was 106 mg/dL, serum sodium was 144 mmol/L, and serum potassium was 3.6 mmol/L. Surprised that the blood glucose had fallen by more than 550

From the Department of Medicine, Duke University Medical Center, Durham, and the Durham Veterans Administration Medical Center, Durham 27710.

mg/dL and the serum potassium had fallen from the high end to the low end of normal in only 90 minutes, we decided to infuse 500 cc of 5% dextrose with 10 mEq of potassium chloride. We (including the patient) were relieved as the cramps gradually subsided over the next hour. At that point, 2 1/2 hours after the IV insulin, the serum glucose was 357 mg/dL, serum sodium was 138 mmol/L, and serum potassium was 3.7 mmol/L.

Discussion

This patient presented to the medicine clinic for routine follow-up, and suffered iatrogenic complications after his physicians responded to his "numbers" without regard for his lack of symptoms from those "numbers." As an endocrinologist and internist who frequently treat hyperglycemia, we were surprised by the dramatic and uncomfortable effect our therapy had on the patient, and subsequently tried to piece together what had happened.

Shock. We wanted to understand our patient's shock, which was manifested by profound hypotension, mental status changes, and peripheral venous collapse. Hypotension has, in fact, been described with insulin therapy, and can occur whether the insulin is administered intravenously, intramuscularly, or subcutaneously.¹ However, this form of hypotension is usually mild, more immediate than in this case, and orthostatic in nature. Insulin decreases plasma volume by about 6% in patients with uncomplicated diabetes mellitus, probably due to a direct or indirect effect of insulin on vascular endothelium, leading to loss of fluid and albumin from the intravascular space.^{2,3} The autonomic nervous system normally compensates for this hypotensive effect of insulin by increasing norepinephrine release.⁴ Patients with autonomic neuropathy are less able to compensate for small changes in plasma volume, and may develop more noticeable changes in blood pressure with insulin injection. Our patient has severe autonomic neuropathy, as manifested by his lack of significant tachycardia with a large drop in blood pressure and his history of hypoglycemia unawareness, and so may be prone to hypotension with even routine insulin therapy.

Our patient's hypotension was profound and delayed by an hour, and was much more likely due to the rapid drop in his plasma glucose. When glucose is shifted intracellularly by insulin therapy, there is a mandatory movement of intravascular water into the intracellular compartment, as required by the Donnan equilibrium. Our patient's serum glucose fell from 670

mg/dL to 106 mg/dL in an hour and a half, reducing plasma osmolality by more than 30 mOsm/kg. We calculate that this caused an estimated 400 mL to 900 mL of water to rapidly move out of his intravascular space (a loss of some 20% to 40% of his intravascular volume).⁵

The increase in serum sodium from 131 mmol/L to 144 mmol/L is further evidence of this loss of intravascular water, since serum sodium concentration is dependent on total extracellular sodium (which had not changed, as the second measurement was done before any intravenous saline was given) divided by intravascular water. Our patient's shock can be explained, then, by two factors. He "lost" a significant amount of intravascular volume rapidly, and was unable to compensate for the resulting drop in blood pressure because of autonomic neuropathy.

Although the patient never became truly hypokalemic, he did have a rapid fall in serum potassium (1.7 mmol/L over 90 minutes). Potassium changes with insulin therapy are well described, and often clinically relevant in the treatment of hyperkalemia and in the management of diabetic ketoacidosis. The potassium-lowering effects of insulin are dose-dependent, with initial uptake of potassium in the splanchnic bed.⁶ The initial

fall in serum potassium coincides with the fall in blood glucose, while a delayed decrease is secondary to catecholamine release and action on peripheral beta receptors.^{7,8} Patients with autonomic neuropathy do not experience the delayed hypokalemic effects of insulin, so our patient's neuropathy may have protected him, to some extent,

"In retrospect, we speculate that the cramps were due to neuromuscular irritability from the rapid transfer of water and glucose into cells, perhaps leading to dilution of intracellular fixed osmoles."

from an even larger drop in serum potassium.

Cramps. We were unable to find any reports of muscle cramping with insulin therapy, despite it being a dramatic event in this case. Although possibly due to hypoperfusion and lactic acid accumulation during hypotension, we were impressed that restoration of the patient's blood pressure with normal saline did nothing to alleviate the cramps. Muscle cramps have been well described in uremic patients during hemodialysis, usually occurring with high ultrafiltration rates. They are relieved by infusion of hypertonic dextrose or hypertonic saline, suggesting that plasma volume contraction is important in their pathogenesis. Heat cramps, which can occur when people sweat profusely, may be caused by a similar mechanism. However, heat cramps require saline for relief (and are not relieved by dextrose), suggesting that hypovolemia and hyponatremia may both be a factor.⁹

During the frenzy of this patient's course, we thought the muscle cramping might have been due to the rapid fall in serum

potassium, so we infused both dextrose and potassium. The cessation of the cramps coincided with the restoration of the "lost" intravascular water with a rise in serum glucose (to 357 mg/dL) that occurred with no increase in serum potassium. In retrospect, we speculate that the cramps were due to neuromuscular irritability from the rapid transfer of water and glucose into cells, perhaps leading to dilution of intracellular fixed osmoles.

Conclusion

We learned several important lessons from this case. The first is that insulin is not a benign drug, and we should not be cavalier in administering it intravenously, especially if we have forgotten much of the physiology we learned in school. The second is to resist treating "numbers." Instead, we should treat the patient (or not treat the patient, if he looks "good" despite "bad" laboratory reports). □

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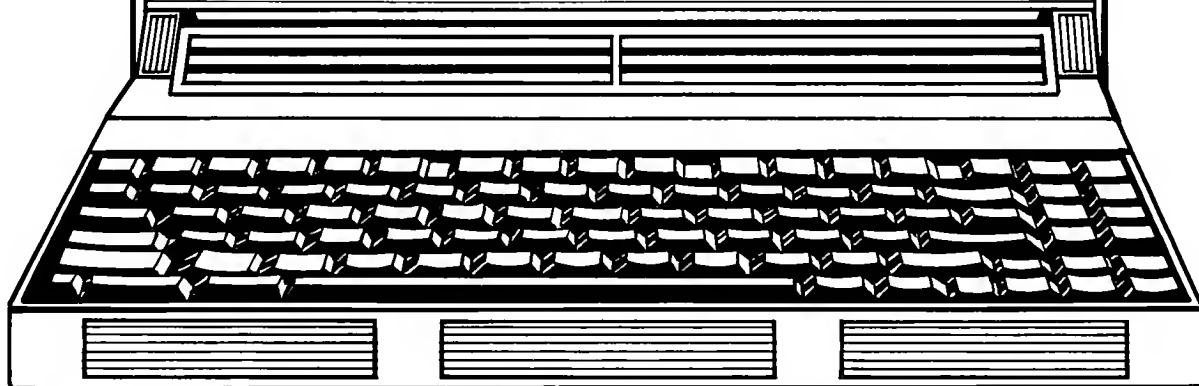
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It's All In Our Minds—Or Is It?

Dorothea's Fables From the Psychiatric/Medical Interface

Donald D. Neish, M.D.

Since the brain is part of the body, it is not surprising that patients may present with "psychiatric" symptoms arising from medical or neurologic illnesses. Failure to diagnose these medical mimics of psychiatric disease puts a patient in extreme peril. Treatment may be inappropriate and even harmful and the correct diagnosis will be missed or at least delayed.

When results are not satisfactory, malpractice attorneys may, on the request of patient or their family members, ask why the therapist was using psychotherapy or psychoactive drugs for a disease that required a specific medication, surgery, or radiation therapy.

The history of psychiatry, as of all branches of medicine, is filled with misunderstandings and false steps. Recall those hypothyroid inmates of asylums whose "myxedema madness," responds so well to small doses of purified thyroid hormone. How many witches were burned, literally and figuratively, until we figured out what temporal lobe epilepsy could do? Today our mental hospitals are not filled with patients suffering from general paresis or other manifestations of neurosyphilis because Alexander Fleming discovered penicillin.

Modern psychiatry texts give excellent expositions about how infections, trauma, congenital disorders, metabolic disorders such as Wilson's disease, endocrine disorders, and malignancies such as brain tumors can present with psychiatric symptoms. The complete list is very long and proves that physicians must always consider more than childhood experiences and ongoing emotional traumas as causes of depressions, dementias, agitations, manias, and the like.

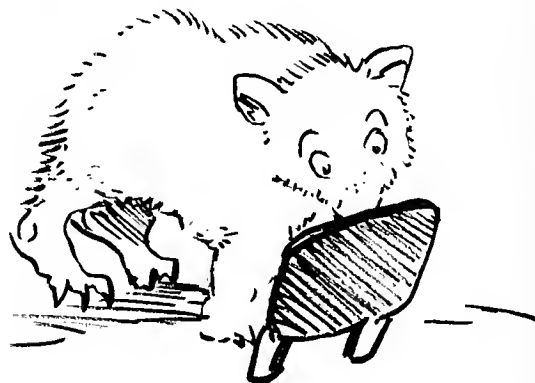
As I thought about how to present this concept in a few case reports I remembered that, through the ages, good writers have used certain formats to get their points across: essays, parables, fairy tales—and fables. The latter is defined as: "a narration

intended to enforce a useful truth, especially one in which animals speak and act like human beings." Searching my library bookshelves late one night, I came across my collection of James Thurber. There was *The Thurber Carnival*, which contains "Fables For Our Time" and some wonderful cartoons, from the *New Yorker* magazine and elsewhere. "Ah, ha," I said to myself. "I have my format."

Here are some cases, disguised as fable to preserve confidentiality, but based on real events from my private practice or from Dorothea Dix Hospital in Raleigh. We all are dedicated to helping our patients, and mental patients deserve our very best efforts, for their life is hard. My use of fable is not meant in any way to diminish these patients as human beings, but to illuminate that we might all see more clearly.

Life Was No Picnic For Mama Bear

Little Mrs. Teddy Bear was very depressed and irritable. She fussed continuously about her weight. Although her legs were staying thin, her middle was not. She was becoming mean and nasty to her family. Therefore, she determined to spend some of



From the Medical Division, Dorothea Dix Hospital, Raleigh, and Assistant Clinical Professor of Medicine and Psychiatry, University of North Carolina at Chapel Hill, Chapel Hill 27599.

the family budget for membership in a health club. Dutifully, she exercised and exercised, while dieting strictly. These efforts did not work. No weight came off and she felt awful.

Noting some slight growth of hair on her face, one day she went in a panic to her gynecologist. He told her, after testing, that there was no androgen-producing tumor of the ovary lurking, so a medical consultation was in order.

On examination the face was a little cheeky, but by no stretch of the imagination a moon face. The affect was agitated/depressed. There was some increase in upper lip hair, but no blood pressure elevation, no acne, no purple striae. Basic chemistries, CBC, and urine and thyroid tests—all normal.

"Is it a glandular condition?" asked Mrs. Bear, hopefully. And, "Why are you staring at my face," tearfully.

"Could you bring me a picture of yourself from a year or more ago?" doctor asked.

She thought he was nuts, but she did it. She brought the pictures from the Teddy Bear's Picnic last year on the Eno River. When he saw the picture and saw how her face had changed, doctor ordered a serum cortisol and urine corticoids. The serum specimen was just a tick or two above the normal range, but the urinary free corticoids were very high. She came to trans-sphenoidal removal of pituitary adenoma, which had caused her Cushing's syndrome. It is a good thing she wasn't given an antidepressant and sent home after the first visit. MORAL: Sometimes, it is a glandular condition.

An Anxious Bird

Mrs. Chickadee was very nervous and trembly. Her husband was continually ruffling her feathers and kicking her around in their nest. She became more and more anxious, and lost weight in spite of good appetite. Her movements were more quick and birdlike than was typical for her kind.

When she was unable to cope because of anxiety and depression, she was hospitalized, thinking it was all her intolerable life situation. At first, her doctors agreed. She had no stare and the thyroid gland was not enlarged and, while she had

a tremor, it was coarse and atypical. But when her sleeping pulse remained over 100 the picture cleared. Her thyroid stimulating hormone was low, the serum thyroxine almost 20.

Dr. Owl, internist, said, "She needs propranolol to cool her down, before she has a bird."

Dr. Wren, psychiatric intern, asked, "Won't that make her even more depressed?"

"We will have to take that chance, lest there be a storm," said Dr. Owl. "We need to buy time, while specific treatment kicks in."

The patient responded nicely to beta blocker and propylthiouracil therapy for her hyperthyroidism.

MORAL: Husbands can be blamed, but not for everything.

Lament of the Little Fox: "I told you I was sick."

Once upon a time there was a little fox who really had mental illness, no doubt of that. Her mother had it and daughter was heading along the same path. So her psychiatrist was not too surprised when she started to complain during a session, "I have snakes crawling around in my chest sometimes."



"Oh?" said her psychiatrist. "Well, we can help you with that."

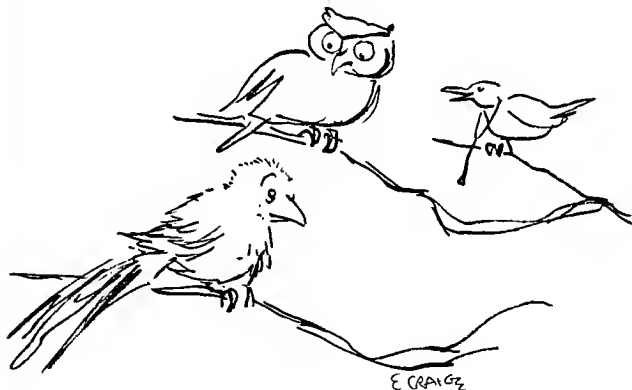
"It's my heart. There is something wrong with my heart."

"Just take your medicine and we'll talk about it some more next week," he said.

The emergency room doctor called him in a few days, saying "Your patient has had an atrial tachycardia. We finally got her converted. Want her to see a cardiologist?"

"By all means," he coughed, uneasily. The appointment was made.

"I have snakes crawling in my chest and there is something



wrong with my heart. I have just spent time in the emergency room," she told the cardiologist.

He made his complete examination—no murmur, gallop, or rub, and the rhythm was sinus. Electrocardiogram and echocardiogram were normal and so were the lab tests. No hyperthyroidism, no pheochromocytoma.

"There is nothing seriously wrong with your heart," he said. "Many young people get tachycardias; they are quite benign. Cut out chocolate, coffee, and cigarettes. And please, follow up with your psychiatrist."

"There must be something wrong with my heart," she cried, and the tachycardias kept coming. They did not respond to anti-psychotic or anti-arrhythmic drug therapy.

One day, for the first time, after a prolonged tachycardia converted, the electrocardiogram showed a typical pattern of the Wolff-Parkinson-White Syndrome.

MORAL: We thought the patient was crying "Wolf!" but there really was a Wolff (or a Parkinson or a White) at the door.

The Lion's Bride

Leo was intimidated by his wife. Although he was King of the Beasts, she gave him no respect. He tried to be a cool cat, dressing in "Colours" by Alexander Julian, but she put him down without mercy. It got so bad that he hated to come home from work, and his mind began to fill with paranoid thoughts. He felt trapped and persecuted. One evening, the voices he heard in his head told him to go for the handgun in the drawer of the bedside table. He shot his wife—in the arm.



"Ha!" she exclaimed. "You can't even shoot straight." But she called the cops and they sent him to the forensic unit for evaluation. There, he got more and more quiet, sleeping more than any lion, cowardly or otherwise, should. On his chemistry panel, his serum calcium was noted to be I4 and the phosphorus

was low. After extensive testing, which included an ultrasound of the neck (read as normal), he consented to exploration of the neck. A large parathyroid adenoma was removed. His mental status improved markedly when the calcium came back to normal. The marriage is another issue.

MORAL: When a King of Beasts turns mean, it might mean an abnormal cation.

Gourmet Raccoon

Mr. Raccoon was not fastidious about his diet. The other animals said, "That dude is indiscriminate, to say the least. He doesn't care about his cholesterol, doesn't watch his salt intake, never chews his food."



"Doesn't floss either," someone added.

Mr. Raccoon heard them talking about him.

"Lay off, guys. Nobody's perfect. Think of my good qualities."

"Like what?" they asked.

"Like I'm never late for an appointment," he said. "Like I'm always the one who has the correct time."

"Yeah, you're right," they said. "By the way, where is that nice little Timex your mother gave you for your birthday?"

The little raccoon just smiled.

A few days later, he was late for an appointment and they found him doubled up with a bellyache. An operation was performed.

In the original



An x-ray of the "real" patient reveals the swallowed watch.

version of *Peter Pan*, Captain Hook could tell the crocodile was near, because it had swallowed a noisily ticking alarm clock. With modern technology, our diagnostic ear must be keener. MORAL: Some things take a licking and keep on ticking.

The most fascinating animal will remain the human one for clinicians. Patients can fool us. Common things are common, but the uncommon diagnoses are out there, ready to challenge us. We must not miss the occasional zebra that lurks among the horses that stampede by us in our daily lives. The mind affects the body, but surely, the reverse is equally true. There lies the challenge. First, do no harm. Second, try to do some good. And be sure you are not missing a medical mimic of psychiatric disease. □

Acknowledgment: Original illustrations by Ernest Craige, M.D., of Chapel Hill.

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Physicians' Forum

To Speak or Not to Speak

Edited by Eugene W. Linfors, M.D.

Journal Editor's Note: Physicians' Forum is a regular feature in the *Journal*/submitted by our contributing editor, Dr. Eugene Linfors. This month, Dr. Linfors asked six physicians how they would have responded to a dilemma facing a physician that was published in the February 6, 1992, edition of *Dear Abby*:

"I am a young physician with a dilemma. Recently, I was seated behind a woman at a concert. I could not help but notice that she had a large and very possibly malignant lesion on the back of her neck. I felt it would be rude to call attention to the lesion while she was with her group of friends. Unfortunately, no further opportunity presented itself, and the woman left before I could speak to her alone.

Later, when speaking to a medical ethicist, I was told that my unsolicited medical opinion would have been inappropriate.

Abby, in a case like this, where a woman's life may have been at risk, I would like to know how you, and your readers—and perhaps other physicians—would have responded."

—An Albuquerque M.D.

Abby's response stated that she disagreed with the medical ethicist that the physician consulted, and would have politely approached the woman to suggest that she visit her physician immediately—a view shared by the majority of our respondents as well. What would *you* have done in this situation? (Dear Abby letter reprinted with permission.)

Robert T. Harris, M.D., F.A.C.P.
Vice President of Medical Affairs
Carolina Physicians' Health Plan
Raleigh 27611-8125

I pondered the situation myself, and then presented the scenario to some colleagues, my wife, and a small group of first-year medical students with whom I meet regularly. All agreed that the physician should have said something. Debates centered around what exactly should have

been said. It struck me from these discussions that these debates were prompted by consideration for the response of the woman with the malignant-looking skin lesion. A number of her possible responses—ranging from grateful acknowledgment to profound indignation—were considered. It occurred to me that it was therefore impossible to predict the response of the woman, particularly since the physician who observed her skin lesion did not know her.

Since the woman's response was unpredictable, and since the likelihood for her potential benefit outweighed potential harm based on the physician's comment, I determined that if the physician felt comfortable doing so from his or her own perspective, it would be appropriate to considerately tell her that such a lesion was observed. The woman's initial response would then dictate any further comments or recommendations by the physician, who would likely be readily

From Durham Internal Medicine Associates, P.A., 4205 Ben Franklin Blvd., Durham 27704.

identifiable as such by the fact that some degree of medical or dermatologic knowledge was necessary to make the observation.

If the woman was unaware of the lesion, and in particular its malignant potential, she might have wanted the physician's advice. If advice were sought, both I and most of those I queried suggested that the physician direct her to her personal or family physician for evaluation or specialty referral if indicated.

I should point out that it is assumed that the physician's observation of the lesion included his or her impression that it did not appear that the lesion had been recently biopsied or otherwise evaluated or treated, in which case the physician should assume that the woman was already aware of the lesion and had taken action to have it evaluated or treated.

In summary, physicians have unique knowledge that must be carefully and selectively used in both their professional and social contacts. In a situation such as this, where medical intervention is called for and it is unclear to the physician that any intervention has occurred, the physician's comments or actions should not be dictated by the unpredictable myriad of potential responses of the person encountered. □

Roy A. Hare, M.D.
Central Internal Medicine, P.A.
Durham 27704

He should say nothing to this stranger. Nor should he stare at it and possibly embarrass her. She may already be aware of the lesion. Furthermore, she may consider it none of his business even after he possibly introduced himself as being a physician.

If she was accompanied by a friend or relative whom you knew well enough, you might consider giving him or her a call in the next day or so about your concern. Even so, only if the lesion was a small, flat, dark lesion suspicious of melanoma would I consider it appropriate for him to become involved in any way. □

Scott Howell, M.D.
Henderson County Internists, P.A.
510 7th Ave., W.
Hendersonville 28739-3565

A medical school professor of mine encountered a similar situation while vacationing at the beach. He chose to inform the stranger of her skin lesion, much to the stranger's appreciation and much to his 12-year-old son's chagrin.

It is well-recognized that physicians' primary duties are the well-being of their patients. It is also recognized that physicians have a duty to promote the well-being of the public. Depending on whether one views "the public" as an amorphous single entity or as a collection of individual single entities, it could be argued that a physician seeing even a stranger with a potentially serious medical condition that may be otherwise unrecognized should point it out.

When I recounted the story of my professor's doings to my father-in-law, he replied, "Gosh, what a great doctor." I would share that view. □

J. Dale Simmons, M.D.
Health Director
Surry County Department of Health
Dobson 27017

I have faced the dilemma proposed in your recent ethics topic regarding making a stranger aware of an obvious and serious medical problem many times. The first occasion was as a junior medical student, when two of my colleagues and I debated the issue for hours. Today this is not a problem, in fact, it is part of my job description. I am health director of Surry County, and it is my job to promote and protect the health of all of the citizens of Surry County.

In the later years of my practice as a private physician, I was not as reluctant to bring an obvious serious problem to the attention of an individual. Always, I attempted to encourage them to seek counsel with their private physician regarding the matter. I also made it a point of calling the physician and informing

him of my recommendation to his patient. If the individual did not have a private physician, I would then give the person a list of several people who might consider evaluating them and giving their opinion.

In all these instances I was careful never to make a definite diagnosis, but only suggest that they appeared to have a problem that might need attention. □

Wendy P. Moeller, M.D.
Eastern Carolina
Internal Medicine, P.A.
Havelock, Pollocksville,
New Bern, and Vanceboro

There would be little hesitation in my mind as to the appropriateness of mentioning to the woman the need to have her lesion looked at. This, in my opinion, is a clear-cut example of acting on good Samaritan impulses. The potential benefit to the woman could be enormous with little, if not nonexistent, risk to me as a stranger, given a casual encounter where issues such as gloves, universal precautions, or the potential for lawsuits (given an undesirable outcome) are virtually nonexistent.

Suggesting that the woman see her personal physician or consult a dermatologist is the entirely appropriate thing to do. I hope when Mr. Goodwrench walks by my car parked in the local grocery store parking lot and notices that my tires are bald, he leaves a note on the windshield suggesting I have them checked by my own garage. □

H.P. Melarangno, Ph.D, M.D.
Charlotte Family
Medical Center, P.A.
Charlotte 28204

I suppose I'm about to put my foot in my mouth, but I would find it very hard not to raise the subject about a possible need for treatment. Yes, I know she's a perfect stranger, but I talk often with strangers. During the course of the conversation I would ask questions regarding life-long

sun exposure, and, in particular, sunburns early in life. By the end of the conversation —although I would never mention the dreaded words “cancer” or “malignancy”—I would most certainly have expressed my medical opinion that this lesion needs medical care by her physician, and I would have urged her to make an appointment as soon as possible. Maybe it’s easier for me as a female practitioner to talk to a strange woman than it would be for a male colleague. □

Editor's Note:

I asked some friends (non-physicians), who conceivably could be on the receiving end of this exchange, and found a similar range of responses. Some thought that they would have been highly offended, although others would have been graciously appreciative. Most of our *Forum* participants advised telling the stranger of the potential danger. I agree. However, it would seem that we should be prepared for some potentially uncomfortable moments if the stranger is less than receptive to the information.

*Eugene W. Linfors, M.D.
Editor, Physicians' Forum*



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September 14-18

Radiological Ultrasound

Place: Winston-Salem
Credit: 25 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

September 17-18

5th Annual Speas Colloquium in Medical Ethics

Place: Davidson, NC
Credit: 6 hours Category I, AMA
Info: Joel Vickers, Dr. P.H., Director of Continuing Medical Education, P.O. Box 32861, Charlotte 28232-2861. 704/355-3942

September 18-19

Embolus Detection 1992

Place: Winston-Salem
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

September 18-20

NC Pediatric Society

Credit: 8 hours Category I, AMA
Info: Office of CME, DUMC, Durham 27710.
919/684-6485

September 20-25

MRI Minifellowship

Place: Winston-Salem
Credit: 32 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

September 21-25

Ultrasound Principles and Instruments

Place: Winston-Salem
Credit: 25 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

September 22-23

HIV Infection Minifellowship

Place: Winston-Salem
Credit: 17 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

September 25-26

Sleep Disorders: Detection and Treatment in Primary Care

Place: Atlantic Beach
Credit: 9 hours Category I, AMA
Info: Mary C. Valand, Office of Continuing Medical Education, Box 7224, Greenville 27835-7224.
919/551-5208

September 25-26

The Business Challenge: Practice Management for New Physicians

Place: Research Triangle Park
Info: W. Alan Skipper, Executive

Assistant, Conferences, North Carolina Medical Society, 222 N. Person St., Raleigh 27611.
919/833-3836

September 28-October 2

Obstetrical Ultrasound

Place: Winston-Salem
Credit: 35 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 1-2

Clinical Tutorial: The Care and Management of the HIV-Infected/AIDS Patient

Place: Greenville
Credit: 15 hours Category I, AMA
Info: Mary C. Valand, Office of Continuing Medical Education, Box 7224, Greenville 27835-7224.
919/551-5208

October 2-3

2nd Annual Vascular Conference

Place: Chapel Hill
Credit: 11 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Building, Chapel Hill 27599-7000. 919/962-2118

October 2-4

2nd Annual PA Satellite Review Course

Place: Winston-Salem
Credit: 18 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 5-9

MRI Minifellowship

Place: Winston-Salem

Credit: 32 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 5-9

Adult Echocardiography

Place: Winston-Salem

Credit: 25 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 7-11

1992 Duke Urologic Assembly

Place: Pinehurst

Credit: 12.5 hours Category I, AMA

Info: Office of CME, DUMC, Durham 27710. 919/684-6485

October 10-11

ACLS Course

Place: Chapel Hill

Credit: 15.5 hours Category I, AMA

Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Building, Chapel Hill 27599-7000. 919/962-2118

October 13

Better Collection Practices

For Your Office

Place: Greensboro

Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, 222 N. Person St., Raleigh 27611. 919/833-3836

October 14

Better Collection Practices

For Your Office

Place: Research Triangle Park

Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, Raleigh 27611. 919/833-3836

October 15

Better Collection Practices

For Your Office

Place: Wilmington

Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, Raleigh 27611. 919/833-3836

October 15

Biannual Cardiology

Update and Review

Place: Asheville

Credit: 5 hours Category I, AMA

Info: Barry Fox, Assoc. Dir. of Continuing Medical Education, 501 Biltmore Ave., Asheville 28801. 704/257-4400

October 16

Ovarian Cancer: Present and

Future Directions in

Clinical Management

Place: Research Triangle Park

Credit: 6 hours Category I, AMA

Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Building, Chapel Hill 27599-7000. 919/962-2118

October 20

Better Collection Practices

For Your Office

Place: Asheville

Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, Raleigh 27611. 919/833-3836

October 22-24

Recent Developments in

Internal Medicine

Place: Atlantic Beach

Credit: 15.5 hours Category I, AMA

Info: Mary C. Valand, Office of Continuing Medical Education, Box 7224, Greenville 27835-7224. 919/551-5208

October 22-24

Duke Fall Symposium in OB/GYN

Place: Asheville

Credit: 13.5 hours Category I, AMA

Info: Office of CME, DUMC,

Durham 27710.

919/684-6485

October 22-25

5th National Conference on Professional Well-Being

Place: San Francisco, CA

Fee: Varies for members, non-members, spouse/guests, students, and residents

Info: Marjorie Harrison, Ph.D., Society for Professional Well-Being, 21 W. Colony Place, Suite 150, Durham, NC 27705. 919/419-0011

October 23-34

Frank R. Lock OB/GYN Symposium

Place: Winston-Salem

Credit: 7.5 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 23-24

BGSM Alumni Weekend

Place: Winston-Salem

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 23-25

13th Annual Mountain

Medical Meeting

Place: Asheville

Credit: 12 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 26-30

Neurovascular Ultrasound

Place: Winston-Salem

Credit: 25 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 29-31**Assisted Technologies****Annual Meeting**

Place: Charlotte

Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Building, Chapel Hill 27599-7000. 919-962-2118

November 2-6**Peripheral Vascular Ultrasound**

Place: Winston-Salem

Credit: 25 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 4-6**3rd Annual Physician****Office Lab Symposium**

Place: Winston-Salem

Credit: 18 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 4-8**North Carolina Medical Society****Annual Meeting**

Place: Pinehurst

Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, 222 N. Person St., Raleigh 27611. 919/833-3836

November 5-8**North Carolina****Dermatology Association**

Place: Pinehurst

Info: H. Mendall Jordan, M.D., Raleigh. 919/781-1001

November 7**North Carolina Society of Pathologists**

Place: Pinehurst

Info: John D. Shelburne, M.D. 919/286-6925

November 7**Fluoroquinolones in the 1990s**

Place: Research Triangle Park

Info: Office of CME, DUMC, Durham 27710. 919/684-6485

November 7**North Carolina Urological Association**

Place: Pinehurst

Info: Floyd Fried, M.D. 919/966-2571

November 6-7**North Carolina Society of****Plastic and Reconstructive Surgery**

Place: Pinehurst

Info: William A. Lambeth, III, M.D. 919/872-2616

November 9-10**Mammography Minifellowship**

Place: Winston-Salem

Credit: 16 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 12**American College of Surgeons****NC Chapter Annual****Cancer Symposium**

Place: Charlotte

Credit: 5 hours Category I, AMA

Info: Joel Vickers, Dr. P.H., Director of Continuing Medical Education, P.O. Box 32861, Charlotte 28232-2861. 704/355-3942

November 12-13**Advanced Cardiac Life Support (ACLS) Provider Course**

Place: Raleigh

Credit: 16 hours, AAFP

Fee: \$150

Info: Helen Creech, R.N., Rex Hospital, 4420 Lake Boone Trail, Raleigh 27607. 919/783-3161

November 12-14**Arts Medicine Seminar**

Place: Winston-Salem

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 16-20**Obstetrical Ultrasound**

Place: Winston-Salem

Credit: 25 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 19-22**Duke Medical Alumni Weekend**

Place: Durham

Info: Office of CME, DUMC, Durham 27710. 919/684-6485

November 20**Breast Cancer: Public Policy, Prevention, and Cost Effectiveness**

Place: Chapel Hill

Credit: 6.5 hours Category I, AMA

Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Building, Chapel Hill 27599-7000. 919/962-2118

November 20-22**Winter Family Physicians Weekend**

Place: Asheville

Info: Deborah W. Alford, NC Academy of Family Physicians, P.O. Box 18469, Raleigh 27619. 919/781-6467

Continuing throughout the year**Geriatric Education Modules**

Place: Durham

Fee: \$10

Info: Geriatric Education Center, Box 3003, DUMC, Durham 27710. 919/684-5149

Send Continuing Medical Education listings to: Jane Whalen, Editorial Assistant, *North Carolina Medical Journal*, Box 3910, Duke University Medical Center, Durham, NC 27710; or fax them to 919-286-9219. For each event, please include title, sponsor, location, fee, credits, contact name, address, and phone number for more information.

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& Gardens 2 yrs		24		17.00	# Home Office Computing		10	19.97	11.97	# Saturday Evening Post		8	15.97	15.97
# Bicycling		10	19.97	10.00 *	House Beautiful		12	17.97	8.99 *	# Scientific American		12	36.00	19.97
Boating		12	24.00	17.97	Inside Sports		12	22.00	14.96		1 yr	12	15.00	12.00
Bon Appetit		12	18.00	15.00	# Jack and Jill (ages 7-10)		8	13.95	9.97	Self	2 yrs	24		22.00
Brides		6	18.00	13.50	Jet Magazine		52	36.00	26.00	# Sesame Street		10	16.97	16.97
Car Craft		12	19.94	11.97	# Kid City (Electric Co.)		10	14.97	14.97	# Seventeen		12	15.95	13.95
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Conde Nast Traveler		12	15.00	12.00	# MacWorld		12	30.00	17.97	Sports Illustrated		54	69.66	34.98
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Field & Stream		12	15.94	8.97	New Woman		12	17.00	12.97	U.S. News	2 yrs	104		39.78
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Football Digest		10	22.00	14.96		1 yr	52	32.00	18.00		2 yrs	24		22.00
Forbes		27	52.00	32.24	# New Yorker	2 yrs	104		34.00	# Video		12	15.00	7.50
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Millions Victimized by Family Members Every Year!

Are you concerned about the effects of family violence and victimization within your community?

Become an advocate within your community for the prevention of family violence.

Violence among family members has reached staggering proportions. Every year more than 2 million cases of child abuse and neglect are reported, between 2 and 4 million women are battered by their spouses, and between 700,000 and 1.1 million of the elderly population are abused.

The American Medical Association has formed a *National Coalition of Physicians Against Family Violence*. Through the *Coalition* the American Medical Association hopes to involve you in activities that address issues of child abuse, sexual assault, domestic violence and elder abuse because you have the unique ability to identify the symptoms, first-hand. By joining the *National Coalition* you will be showing your concern about the effects of family violence and victimization, and will become a committed advocate within your community for the prevention of family violence.

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- be informed about local contacts and referrals
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- be provided with information regarding model educational programs
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- receive an official membership card and frameable poster alerting your patients of your interest in and concern for this problem.

The only **cost** to you **is your commitment** to help curb this problem. Simply complete the membership application form below and mail to the Department of Mental Health, American Medical Association, 515 N. State Street, Chicago, IL 60610.

Yes, include my name in the *Coalition's* membership

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Address _____

City/State/Zip _____ Telephone # _____

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Auxiliary Member ☐ Yes ☐ No

Other _____

Area of interest within Family Violence: ☐ Child Abuse ☐ Sexual Assault ☐ Domestic Violence

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Dr. Aliza Lifshitz, Internist, Los Angeles, California,
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FAMILY PHYSICIAN: to join busy solo doctor in suburban Raleigh, NC. Excellent working conditions, beautiful office, competitive compensation, good hospitals. Prefer recent FP residency graduate, but other primary care doctors considered. Please respond with CV or resumé to Office Manager, 605 Benson Road, Garner, NC 27529.

STUDENT HEALTH SERVICE: North Carolina State University desires two BC/BE physicians in FP, IM, or PED. One is a nine-month permanent position, to be filled by January 1993, or as quickly as possible. Second position is for 12 months effective July 1993; applications by 11/1/92. Send letter of interest, CV, and name, address, and phone numbers for three references to Administrative Director, Student Health Service, NCSU, Box 7304, Raleigh, NC 27695.

PEDIATRICIAN NEEDED IMMEDIATELY: in beautiful mountain town of Boone, NC. New office building 1/2 block from 160-bed hospital. ASU University. Skiing. Near Grandfather Mountain. Call Dr. William B. Horn, Rt. 6, Box 204, Boone, NC 28607. 704/264 5476 (home), 704/264-5385 (office).

OFFICE SPACE: Easy access to Charlotte or Gastonia on Highway 74, prime location for family practice or specialty, 3,800 square foot, will finish to suit. Call Dr. David Demperio at 704/825-9799.

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For members of the North Carolina Medical Society, classified rates are: \$15 for the first 25 words, 25 cents for each additional word. For non-members, rates are \$25 for the first 25 words, 25 cents for each additional word. All ad copy must be received by the 10th of the month preceding publication. Direct inquiries to: *North Carolina Medical Journal*, Classified Advertising, Box 3910, Duke University Medical Center, Durham, NC 27710; 919-286-6412, fax: 919-286-9219.

Aphorisms of the Month

Edited by Daniel Sexton, M.D.

Lawyers and the Law

Law is an ass; an idiot.

—Charles Dickens

Doctors are just the same as lawyers; the only difference is that lawyers merely rob you whereas doctors rob you and kill you too.

—Anton Chekhov; *Ivanov*, 1887

A good lawyer is a bad neighbor.

—French proverb

Law is a bottomless pit.

—John Arbuthnot, *M.D.*; title of pamphlet, 1712

You're an attorney. It's your duty to lie, conceal, and distort everything, and slander everybody.

—Jean Giraudoux; *The Madwoman of Chaillot*, 1945

There is no better way of exercising the imagination than the study of law. No poet ever interpreted nature as freely as a lawyer interprets truth.

—Jean Giraudoux; *Tiger at the Gates*, 1935

A man may as well open an oyster without a knife as a lawyer's mouth without a fee.

—Barten Holyday

Send your favorite aphorisms (typed and double-spaced) to: Aphorisms of the Month, Attn: Daniel Sexton, M.D., Box 3605, DUMC, Durham, NC 27710.

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*The recommended starting dose for Calan SR is 180 mg once daily. Dose titration will be required in some patients to achieve blood pressure control. A lower initial starting dosage of 120 mg/day may be warranted in some patients (eg, the elderly, patients of small stature). Dosages above 240 mg daily should be administered in divided doses. Calan SR should be administered with food.

†Constipation, which is easily managed in most patients, is the most commonly reported side effect of Calan SR.

‡Verapamil should be administered cautiously to patients with impaired renal function.

BRIEF SUMMARY

Contraindications: Severe LV dysfunction (see *Warnings*), hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no pacemaker is present), 2nd- or 3rd-degree AV block (if no pacemaker is present), atrial flutter/fibrillation with an accessory bypass tract (eg, WPW or LGL syndromes), hypersensitivity to verapamil.

Warnings: Verapamil should be avoided in patients with severe LV dysfunction (eg, ejection fraction < 30%) or moderate to severe symptoms of cardiac failure and in patients with any degree of ventricular dysfunction if they are receiving a beta-blocker. Control milder heart failure with optimum digitalization and/or diuretics before Calan SR is used. Verapamil may occasionally produce hypotension. Elevations of liver enzymes have been reported. Several cases have been demonstrated to be produced by verapamil. Periodic monitoring of liver function in patients on verapamil is prudent. Some patients with paroxysmal and/or chronic atrial flutter/fibrillation and an accessory AV pathway (eg, WPW or LGL syndromes) have developed an increased antegrade conduction across the accessory pathway bypassing the AV node, producing a very rapid ventricular response or ventricular fibrillation after receiving I.V. verapamil (or digitalis). Because of this risk, oral verapamil is contraindicated in such patients. AV block may occur (2nd- and 3rd-degree, 0.8%). Development of marked 1st-degree block or progression to 2nd- or 3rd-degree block requires reduction in dosage or, rarely, discontinuation and institution of appropriate therapy. Sinus bradycardia, 2nd-degree AV block, sinus arrest, pulmonary edema and/or severe hypotension were seen in some critically ill patients with hypertrophic cardiomyopathy who were treated with verapamil.

Precautions: Verapamil should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of overdosage. Verapamil may decrease neuromuscular transmission in patients with Duchenne's muscular dystrophy and may prolong recovery from the neuromuscular blocking agent vecuronium. It may be necessary to decrease verapamil dosage in patients with attenuated neuromuscular transmission. Combined therapy with beta-adrenergic blockers and verapamil may result in additive negative effects on heart rate, atrioventricular conduction and/or cardiac contractility; there have been reports of excessive bradycardia and AV block, including complete heart block. The risks of such combined therapy may outweigh the benefits. The combination should be used only with caution and close monitoring. Decreased metoprolol and propranolol clearance may occur when either drug is administered concomitantly with verapamil. A variable effect has been seen with combined use of atenolol. Chronic verapamil treatment can increase serum digoxin levels by 50% to 75% during the first week of therapy, which can result in digitalis toxicity. In patients with hepatic cirrhosis, verapamil may reduce total body clearance and extrarenal clearance of digoxin. The digoxin dose should be reduced when verapamil is given, and the patient carefully monitored. Verapamil will usually have an additive effect in patients receiving blood-pressure-lowering agents.

References: 1. Data on file, Searle. 2. Edmonds D, Würth JP, Baumgart P, et al. Twenty-four-hour monitoring of blood pressure during calcium antagonist therapy. In: Fleckenstein A, Laragh SH, eds. *Hypertension—the Next Decade: Verapamil In Focus*. New York, NY: Churchill Livingstone; 1987:94-100. 3. Midtbo KA. Effects of long-term verapamil therapy on serum lipids and other metabolic parameters. *Am J Cardiol*. 1990;66:131-151. 4. Fagher B, Henningsen N, Hulthén L, et al. Antihypertensive and renal effects of enalapril and slow-release verapamil in essential hypertension. *Eur J Clin Pharmacol*. 1990;39(suppl 1):S41-S43. 5. Schmieder RE, Messerli FH, Garavaglia GE, et al. Cardiovascular effects of verapamil in patients with essential hypertension. *Circulation*. 1987;75:1030-1036. 6. Midtbo K, Lauve O, Hals O. No metabolic side effects of long-term treatment with verapamil in hypertension. *Angiology*. 1988;39:1025-1029.

Disopyramide should not be given within 48 hours before or 24 hours after verapamil administration. Concomitant use of flecainide and verapamil may have additive effects on myocardial contractility, AV conduction, and repolarization. Combined verapamil and quinidine therapy in patients with hypertrophic cardiomyopathy should be avoided, since significant hypotension may result. Concomitant use of lithium and verapamil may result in an increased sensitivity to lithium (neurotoxicity), with either no change or an increase in serum lithium levels; however, it may also result in a lowering of serum lithium levels. Patients receiving both drugs must be monitored carefully. Verapamil may increase carbamazepine concentrations during combined use. Rifampin may reduce verapamil bioavailability. Phenobarbital may increase verapamil clearance. Verapamil may increase serum levels of cyclosporin. Verapamil may inhibit the clearance and increase the plasma levels of theophylline. Concomitant use of inhalation anesthetics and calcium antagonists needs careful titration to avoid excessive cardiovascular depression. Verapamil may potentiate the activity of neuromuscular blocking agents (curare-like and depolarizing); dosage reduction may be required. There was no evidence of a carcinogenic potential of verapamil administered to rats for 2 years. A study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor, and delivery only if clearly needed. Verapamil is excreted in breast milk; therefore, nursing should be discontinued during verapamil use.

Adverse Reactions: Constipation (7.3%), dizziness (3.3%), nausea (2.7%), hypotension (2.5%), headache (2.2%), edema (1.9%), CHF, pulmonary edema (1.8%), fatigue (1.7%), dyspnea (1.4%), bradycardia: HR < 50/min (1.4%), AV block: total 1°-2° (1.2%), 2° and 3° (0.8%), rash (1.2%), flushing (0.6%), elevated liver enzymes, reversible non-obstructive paralytic ileus. The following reactions, reported in 1.0% or less of patients, occurred under conditions where a causal relationship is uncertain: angina pectoris, atrioventricular dissociation, chest pain, claudication, myocardial infarction, palpitations, purpura (vasculitis), syncope, diarrhea, dry mouth, gastrointestinal distress, gingival hyperplasia, ecchymosis or bruising, cerebrovascular accident, confusion, equilibrium disorders, insomnia, muscle cramps, paresthesia, psychotic symptoms, shakiness, somnolence, arthralgia and rash, exanthema, hair loss, hyperkeratosis, macules, sweating, urticaria, Stevens-Johnson syndrome, erythema multiforme, blurred vision, gynecomas- tia, galactorrhea/hyperprolactinemia, increased urination, spotty menstruation, impotence.

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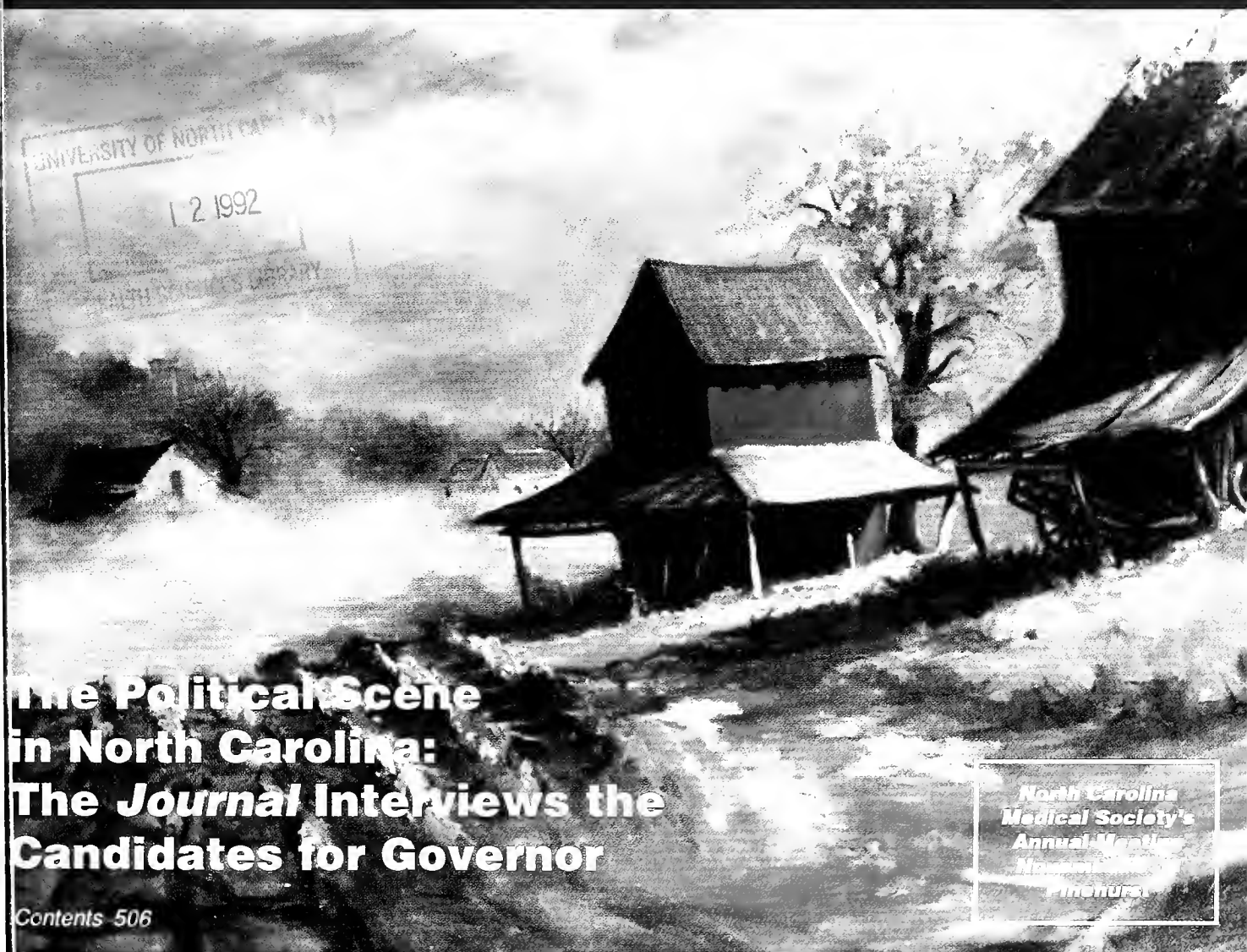
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The
Official Journal
of the
North Carolina
Medical Society
October 1992
Volume 53
Number 10

North Carolina Medical Journal

For Doctors and their Patients



**The Political Scene
in North Carolina:
The *Journal* Interviews the
Candidates for Governor**

**North Carolina
Medical Society's
Annual Meeting
November 1-4
Pinehurst**

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JACK AMIRIAN *A Moment In Time*



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ORIGINAL OIL PAINTING AVAILABLE

RANGER WILLIE by Jack Amirian

March 21, 1865

You're sitting in the driver's seat of the ambulance ordered to transport Willie, a perfect view caught in a moment of time, as General Hardee consoles his wounded son, among generals: Wade Hampton, SC; Joseph Wheeler, GA; Robert Hoke, NC; and Commander Joseph Johnston, VA. While the medical staff applies final treatment to Willie's abdominal wound, supportive members of Terry's Texas Rangers stand by.

For years, it was Willie's ambition to be a member of the famed "Terry's Texas Rangers" 8th Texas Cavalry. Earlier, he had run away from a military school in Georgia to enlist. Now for his 16th birthday, Willie turned up at Bentonville, NC with the same request. This time, his father, Gen. William Hardee reluctantly agreed, and said to Capt. Kyle of Co. D "Swear him into service in your company, as nothing else will satisfy." Just hours later, Willie kissed his father, and rode into battle.

This was the 3rd and last day of the battle at Bentonville, the last major battle of the war between the states. The Confederate Army of 22,000 men, (while facing a Federal Army of 56,000 with 40,000 more within support distance) were carefully guarding their only line of retreat, Mill Creek Bridge. At 4 p.m. on the 21st of March, 1865 – an overanxious Gen. Mower of Sherman's 17th Corps – drove his division through a line of dismounted cavalry, over-ran two rifle pits, and charged through a field hospital, within 200 yds. of Gen. Johnston's headquarters, and 300 yds. from Mill Creek Bridge. Confederate reinforcements were sent to the scene, but it was doubtful they could save the bridge, and Johnston's Army.

Willie's moment of glory had finally arrived. Suddenly, Willie, among

eighty members of Terry's Texas Rangers, with reins in mouth and a pistol in each hand, attacked Mower's left flank. Simultaneously a cavalry brigade under Gen. Hampton pitched in from the right. A Georgian Infantry brigade from McLaw's division assaulted the Federal front, and Gen. Wheeler, leading 500 Alabamian Cavalrymen moved in on Mower's rear. Gen. Mower's much larger division, suffering heavy losses, and nearly surrounded, was forced to retreat to his original position.

Upon Gen. Hardee's return from battle, and just after saying to a passing lieutenant "That was nip & tuck, and for a while, I thought tuck had it," he noticed Willie being carried on a litter. After spending a few moments with his only son, Willie was transported by ambulance over the saved bridge, and on to Hillsborough, NC.

Just three days later, with his father at his bedside, Willie passed away. After a military funeral, Willie Hardee was buried at St. Matthew's Episcopal Church in Hillsborough, NC where his grave site still remains.

This painting is a tribute to the gallantry of Willie and entitled as an extension of a short-lived status he paid so dearly to attain... Ranger Willie.

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For Doctors and their Patients

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North Carolina Medical Journal

FOR DOCTORS AND THEIR PATIENTS

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On the cover: Detail from "Sunlight on the Collard Patch," (acrylic, 1989) by Bob Pittman, Greenville. The Volunteer Auxiliary of Pitt County Memorial Hospital purchased this painting, which hangs in the hospital's admissions lobby in Greenville.

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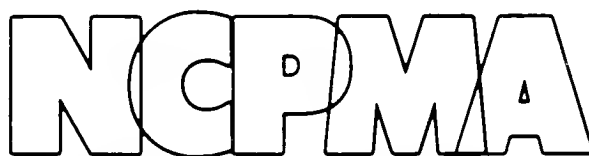
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Letters to the Editor

HIV-Infected Pediatric Patients To the Editor:

In the August issue of the *Journal* you published a thoughtful paper by authors from Wilmington relating their experience with HIV infection at New Hanover Regional Medical Center (NC Med J 1992;53:416-418). Absent from the article was any mention of pediatric patients. They have focused totally on the perspective of the internist. From experience with our referral patients at the Duke Pediatric Infectious Diseases Clinic, we know of at least 25 HIV-infected children (under age 13) living in this same area. There are a number of devoted and skilled pediatricians in Wilmington and environs who are willing to provide sensitive primary care for these infants and children and to whom we provide consultative and collaborative support with investigative therapy for these youngsters.

It would be inappropriate to omit any mention of perinatal HIV infection in New Hanover County because heterosexual transmission is rising at a more rapid rate than any of the other defined routes both there and across the nation. Infected women place approximately 30% of their newborns at risk of infection. The obstetric and pediatric populations of New Hanover Regional Medical Center merit surveillance and evaluation.

Samuel L. Katz, M.D.
Wilbur C. Davison Professor
Duke University Medical Center
Durham, NC 27710

From the Authors:

Dr. Katz's letter points out the important contribution that pediatricians are making in caring for HIV-infected patients. Our study included only in-patients who had an established diagnosis of HIV disease while hospitalized at New

Hanover Regional Medical Center (NHRMC). There are many more HIV-infected individuals in this community who have not required hospitalization at NHRMC, or who were not known to be infected while hospitalized. Many additional physicians may be involved in the care of these patients. Although it would be helpful to have data about these additional patients, acquiring these data would require the review of office records of all primary care physicians in the area, a somewhat difficult task.

Peter C. Ungaro, M.D.
John K. Keku, M.D.
Jane Ranney, Ph.D.
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Wilmington, NC 28402-9025

Focus on Smokeless Tobacco To the Editor:

I enjoyed the article by Dr. Adam Goldstein on youth and tobacco (NC Med J 1992;53:411-414). The use of smokeless tobacco has been a long-term occurrence in North Carolina, especially among older women who began this habit as young adults when smoking was less acceptable for women. Many of these people have now become oral cavity carcinoma patients. In fact, it would seem that we have one of the largest endemic rates of this disease associated with the use of smokeless tobacco in the nation.

Much of the epidemiologic work on the use of smokeless tobacco and the association of smokeless tobacco usage with oral cancers has been done through UNC-Chapel Hill and East Carolina University. National statistics show that while smoked tobacco usage is slowly decreasing in popularity, the use of smokeless tobacco is rapidly increasing. This is particularly true in the young adult

male of high school and younger age. If our young population continues to use this product, as would be expected from its addictive characteristics, then we may see an increased occurrence of oral cavity carcinoma in this population in the future. I would urge the North Carolina Medical Society Tobacco Control Task Force to take an increased interest in the problem of smokeless tobacco usage and allocate more resources for education and prevention directed toward our young people.

W. Fred McGuirt, M.D., Professor
Department of Otolaryngology
Bowman Gray School of Medicine
Winston-Salem, NC 27103

World War II Volunteerism To the Editor:

In a history of the work performed by 3,000 conscientious objectors as volunteers in mental hospitals during World War II, I have included a section describing the unique contributions of the unit that was in service at that time at Duke University Hospital.

In preparing the material, I have drawn upon an article that appeared in the July 1985 issue of the *Journal* by Louis E. Swanson and James F. Gifford, Jr., Ph.D., which offers a retrospective of the service rendered by those in the unit noted above.

My manuscript has been accepted for publication by The American Psychiatric Press and The Herald Press for release in the summer of 1993. I would greatly appreciate your permission to make use of excerpts from this article.

Alex Sareyan, President
Mental Health Materials Center
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Bronxville, NY 10708

From the Editor:

We were happy to grant Mr. Sareyan permission to excerpt text from "Conscientious Objection and Clinical Care: A History of Civilian Public Service Camp No. 61 at Duke University, 1942-1946," (NC Med J 1985;46:419-423), and we were pleased that the article proved useful in his research.

More on Membership

To the Editor:

Congratulations to Dr. Neelon on his first year as editor of the *Journal*. The recent article by Grimes Byerly, M.D. (NC Med J 1992;53:431-432), certainly highlighted the excellent membership program of the Medical Society. If all our Peer-to-Peer physicians exhibited the same energy in recruitment we would not have a problem with membership.

Several of our state members have won sports jackets and other awards in connection with the AMA recruitment programs.

The North Carolina Medical Society has increased its AMA membership every year for approximately 15 years but has recently lost a delegate and an alternate based on the fact that with increased state membership, we will need even more AMA members from North Carolina to maintain 75% AMA members within our state society.

Keep up the good work!

John Glasson, M.D.
615 Swift Ave.
Durham, NC 27701

NC PA Survey

To the Editor:

It was with great interest that I read "A Niche for the Journal" in the August issue (NC Med J 1992;53:426). I agree that the *Journal* has a definite place for a spectrum of articles that are often not found in larger, national medical journals, but offer the reader information of enduring value and refreshing viewpoint. I have read and appreciated the *Journal* for the 15 years I have been a physician assistant.

In 1984 and 1986, I co-authored articles in the *Journal* that updated physicians on the PA profession in North Carolina. Last year, the North Carolina Academy of Physician Assistants asked me to look again at how the PA profession has grown and changed in the 10 years since our 1982 statewide survey. We conducted another statewide PA survey in the early months of this year. At this time, we are preparing our analysis of the data and graphics for publication.

This 1992 North Carolina Physician Assistant Survey information has not been published or submitted to any other journal. Co-author Ann Hines and I would like to submit a manuscript for consideration for publication in the *Journal*. We believe it will be of interest to physicians in North Carolina who employ PAs or who might be considering using PAs in their practice compared with similar surveys done in 1982 and 1986.

Wayne W. VonSeggen, PA-C
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3 Keswick Court
Winston-Salem, NC 27103

From the Editor:

We would be happy to consider publishing the results of your survey when they are available.

Guidelines for Letters

The *North Carolina Medical Journal* encourages feedback in the Letters to the Editor column. Letters are published at the discretion of the editor as space permits. All letters are subject to editing and abridgment. Letters should not exceed 500 words; longer letters are welcome, however, and we will consider them for publication elsewhere in the *Journal*.

Letters must be typed, double-spaced, signed, dated, and include the author's phone number and address. References, if any, should be held to a minimum, preferably four or fewer.

We normally do not return letters, nor do we notify authors of our intent to publish them, except in the event that we feel a letter deserves additional comment by the editor or another medically qualified expert.

Want to Write For the Journal?

Join the editorial staff of the **North Carolina Medical Journal** for a writer's workshop on Saturday, November 7, from 9 a.m. to noon, held at the Holiday Inn in Pinehurst, NC, during the Annual Meeting of the North Carolina Medical Society.

Points will include:

✓ **Subjects:** What kinds of articles are suitable for publication in the *Journal*?

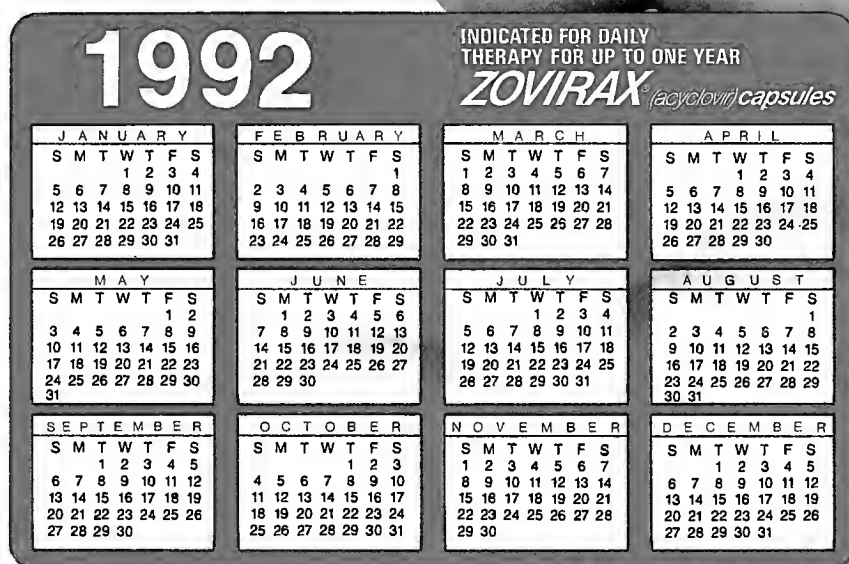
✓ **Writing:** Tips on getting your message across with clarity and conciseness.

✓ **Preparation:** How to develop an article idea into a well-written and referenced manuscript.

✓ **Publication:** Tracking the manuscript through the review process and editorial production.

To attend, complete the workshop registration form in your Annual Meeting registration packet, or call the Journal at 919-286-6410.

ANNOUNCING A GREAT YEAR AHEAD FOR GENITAL HERPES PATIENTS



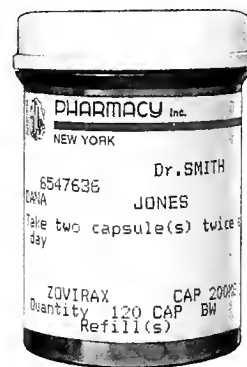
1-YEAR INDICATION FOR DAILY THERAPY

Genital herpes patients can look forward to a great year ahead. Results of a recent clinical study show a lesion-free year for nearly half the patients treated with ZOVIRAX Capsules 400 mg b.i.d.*¹ For all ZOVIRAX Capsule recipients, recurrences during the study year were limited to a mean of 1.8, compared with a mean of 11.4 for placebo recipients.¹

Daily use was also shown to be well tolerated. And this extended clinical study demonstrated no evidence of cumulative toxicity and no change in acyclovir sensitivity.^{1,2}

An appropriate patient profile for continuous suppressive therapy would include the patient with frequent recurrences (6 or more outbreaks per year); the patient with severe recurrences; and the patient emotionally impaired by genital herpes recurrences.

Prescribe daily ZOVIRAX Capsule therapy...and help keep your patients lesion-free longer.[†]



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(acyclovir) Capsules

KEEPS GENITAL HERPES PATIENTS LESION-FREE LONGER[†]

*Alternate maintenance regimens range from 200 mg t.i.d. to 200 mg five times daily.

[†]In a controlled study of 3 years' duration, 45%, 52%, and 63% of patients remained free of recurrences in the first, second, and third years, respectively.³

Please see brief summary of prescribing information on adjacent page.

ZOVIRAX® CAPSULES ZOVIRAX® TABLETS ZOVIRAX® SUSPENSION (ACYCLOVIR)

BRIEF SUMMARY

CONTRAINDICATIONS: Zovirax Capsules, Tablets, and Suspension are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulations.

WARNINGS: Zovirax Capsules, Tablets, and Suspension are intended for oral ingestion only. **PRECAUTIONS: General:** Zovirax has caused decreased spermatogenesis at high parenteral doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see **PRECAUTIONS — Carcinogenesis, Mutagenesis, Impairment of Fertility**). The recommended dosage should not be exceeded. Exposure of herpes simplex and varicella-zoster isolates to acyclovir *in vitro* can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in man must be borne in mind when treating patients. The relationship between the *in vitro* sensitivity of herpes simplex or varicella-zoster virus to acyclovir and clinical response to therapy has yet to be established (see full prescribing information). Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of acyclovir may result in selection of resistant viruses which may not fully respond to continued acyclovir therapy. Caution should be exercised when administering Zovirax to patients receiving potentially nephrotoxic agents since this may increase the risk of renal dysfunction. **Drug Interactions:** Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced. The clinical effects of this combination have not been studied. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** The data presented below include references to peak steady state plasma acyclovir concentrations observed in humans treated with 800 mg given orally 6 times a day (dosing appropriate for treatment of herpes zoster) or 200 mg given orally 6 times a day (dosing appropriate for treatment of genital herpes). Plasma drug concentrations in animal studies are expressed as multiples of human exposure to acyclovir at the higher and lower dosing schedules (see full prescribing information). Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of up to 450 mg/kg administered by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors. At 450 mg/kg/day, plasma concentrations were 3 to 6 times human levels in the mouse bioassay and 1 to 2 times human levels in the rat bioassay. Acyclovir was tested in two *in vitro* cell transformation assays. Positive results were observed at the highest concentration tested (31 to 63 times human levels) in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative (40 to 80 times human levels) in the other, possibly less sensitive, transformation assay. In acute cytogenetic studies, there was an increase, though not statistically significant, in the incidence of chromosomal damage at maximum tolerated parenteral doses of acyclovir (100 mg/kg) in rats (62 to 125 times human levels) but not in Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters (380 to 760 times human levels). In addition, no activity was found after 5 days dosing in a dominant lethal study in mice (36 to 73 times human levels). In all 4 microbial assays, no evidence of mutagenicity was observed. Positive results were obtained in 2 of 7 genetic toxicity assays using mammalian cells *in vitro*. In human lymphocytes, a positive response for chromosomal damage was seen at concentrations 150 to 300 times the acyclovir plasma levels achieved in man. At one locus in mouse lymphoma cells, mutagenicity was observed at concentrations 250 to 500 times human plasma levels. Results in the other five mammalian cell loci follow: at 3 loci in a Chinese hamster ovary cell line, the results were inconclusive at concentrations at least 1850 times human levels; at 2 other loci in mouse lymphoma cells, no evidence of mutagenicity was observed at concentrations at least 1500 times human levels. Acyclovir has not been shown to impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, s.c.). In the mouse study plasma levels were 9 to 18 times human levels, while in the rat study they were 8 to 15 times human levels. At a higher dose in the rat (50 mg/kg/day, s.c.), there was a statistically significant increase in post-implantation loss, but no concomitant decrease in litter size. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day (16 to 31 times human levels). No effect upon implantation efficiency was observed when the same dose was administered intravenously (53 to 106 times human levels). In a rat peri- and postnatal study at 50 mg/kg/day s.c. (11 to 22 times human levels), there was a statistically significant decrease in the group mean numbers of corpora lutea, total implantation sites and live fetuses in the F₁ generation. Although not statistically significant, there was also a dose-related decrease in group mean numbers of live fetuses and implantation sites at 12.5 mg/kg/day and 25 mg/kg/day, s.c. The intravenous administration of 100 mg/kg/day, a dose known to cause obstructive nephropathy in rabbits, caused a significant increase in fetal resorptions and a corresponding decrease in litter size (plasma levels were not measured). However, at a maximum tolerated intravenous dose of 50 mg/kg/day in rabbits (53 to 106 times human levels), no drug-related reproductive effects were observed. Intraperitoneal doses of 80 or 320 mg/kg/day acyclovir given to rats for 6 and 1 months, respectively, caused testicular atrophy. Plasma levels were not measured in the one month study and were 24 to 48 times human levels in the six month study. Testicular atrophy was persistent through the 4-week postdose recovery phase after 320 mg/kg/day; some evidence of recovery of sperm production was evident 30 days postdose. Intravenous doses of 100 and 200 mg/kg/day acyclovir given to dogs for 31 days caused aspermatogenesis. At 100 mg/kg/day plasma levels were 47 to 94 times human levels, while at 200 mg/kg/day they were 159 to 317 times human levels. No testicular abnormalities were seen in dogs given 50 mg/kg/day i.v. for one

month (21 to 41 times human levels) and in dogs given 60 mg/kg/day orally for one year (6 to 12 times human levels). **Pregnancy: Teratogenic Effects:** Pregnancy Category C. Acyclovir was not teratogenic in the mouse (450 mg/kg/day, p.o.), rabbit (50 mg/kg/day, s.c. and i.v.) or in standard tests in the rat (50 mg/kg/day, s.c.). These exposures resulted in plasma levels 9 and 18, 16 and 106, and 11 and 22 times, respectively, human levels. In a non-standard test in rats, there were fetal abnormalities, such as head and tail anomalies, and maternal toxicity. In this test, rats were given 3 s.c. doses of 100 mg/kg acyclovir on gestation day 10, resulting in plasma levels 63 and 125 times human levels. There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Although acyclovir was not teratogenic in standard animal studies, the drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination. **Nursing Mothers:** Acyclovir concentrations have been documented in breast milk in two women following oral administration of Zovirax and ranged from 0.6 to 4.1 times corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg/day. Caution should be exercised when Zovirax is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness in children less than 2 years of age have not been adequately studied. **ADVERSE REACTIONS—Herpes Simplex: Short-Term Administration:** The most frequent adverse reactions reported during clinical trials of treatment of genital herpes with orally administered Zovirax were nausea and/or vomiting in 8 of 298 patient treatments (2.7%) and headache in 2 of 298 (0.6%). Nausea and/or vomiting occurred in 2 of 287 (0.7%) patients who received placebo. Less frequent adverse reactions, each of which occurred in 1 of 298 patient treatments with orally administered Zovirax (0.3%), included diarrhea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, inguinal adenopathy, medication taste and sore throat. **Long-Term Administration:** The most frequent adverse reactions reported in a clinical trial for the prevention of recurrences with continuous administration of 400 mg (two 200 mg capsules) 2 times daily for 1 year in 586 patients treated with Zovirax were: nausea (4.8%), diarrhea (2.4%), headache (1.9%) and rash (1.7%). The 589 control patients receiving intermittent treatment of recurrences with Zovirax for 1 year reported diarrhea (2.7%), nausea (2.4%), headache (2.2%) and rash (1.5%). The most frequent adverse reactions reported during the second year by 390 patients who elected to continue daily administration of 400 mg (two 200 mg capsules) 2 times daily for 2 years were headache (1.5%), rash (1.3%) and paresthesia (0.8%). Reactions reported by 329 patients during the third year include asthenia (1.2%), paresthesia (1.2%) and headache (0.9%). **Herpes Zoster:** The most frequent adverse reactions reported during three clinical trials of treatment of herpes zoster (shingles) with 800 mg of oral Zovirax 5 times daily for 7 to 10 days in 323 patients were: malaise (11.5%), nausea (8.0%), headache (5.9%), vomiting (2.5%), diarrhea (1.5%) and constipation (0.9%). The 323 placebo recipients reported malaise (11.1%), nausea (11.5%), headache (11.1%), vomiting (2.5%), diarrhea (0.3%) and constipation (2.4%). **Chickenpox:** The most frequent adverse events reported during three clinical trials of treatment of chickenpox with oral Zovirax in 495 patients were: diarrhea (3.2%), abdominal pain (0.6%), rash (0.6%), vomiting (0.6%), and flatulence (0.4%). The 498 patients receiving placebo reported: diarrhea (2.2%), flatulence (0.8%), and insomnia (0.4%). **Observed During Clinical Practice:** Based on clinical practice experience in patients treated with oral Zovirax in the U.S., spontaneously reported adverse events are uncommon. Data are insufficient to support an estimate of their incidence or to establish causation. These events may also occur as part of the underlying disease process. Voluntary reports of adverse events which have been received since market introduction include: **General:** fever, headache, pain, peripheral edema **Digestive:** diarrhea, elevated liver function tests, gastrointestinal distress, nausea **Hemic and Lymphatic:** leukopenia, lymphadenopathy **Nervous:** confusion, dizziness, hallucinations, paresthesia, somnolence **Musculoskeletal:** myalgia **Skin:** alopecia, pruritus, rash, urticaria **Special Senses:** visual abnormalities

February 1992

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Responses to:

"The Content of One Doctor's Practice"

Editor's Note: Dr. William G. Porter, of the Department of Internal Medicine, Carolinas Medical Center, Charlotte, sent the following response to the *Journal* regarding Dr. William H. Howell's August article titled, "The Content of One Doctor's Practice: Relevance of the Biopsychosocial Model," (NC Med J 1992;53:404-409). We then invited four physicians to offer their opinions on the same subject, which we append here. They are: Dr. Lloyd Michener, Department of Community and Family Medicine, and Dr. Jeffrey G. Wong, Department of Medicine, both of the Duke University Medical Center, Durham; Dr. Peter R. Lichstein, Department of Medicine, East Carolina University School of Medicine, Greenville; and Dr. Edward B. Yellig, Raleigh Internal Medicine Associates, P.A., Raleigh.

The doctors' remarks are part of a new section, **Commentaries**, which consists of reflections about previously published papers. **Commentaries** represents a kind of extended dialogue between authors and readers that we would like to encourage. We look forward to receiving your contributions, now and in the future, to make this a regular feature in the *Journal*.

Preserving the Biopsychosocial Model

In his article in the August 1992 issue of the *Journal*,¹ Dr. William Howell describes how Engel's biopsychosocial model² has helped him in the practice of general internal medicine. Engel challenged physicians to adopt a model of medical thinking that would take into account not only the classical biomedical definition of illness, but also the psychosocial conditions unique to the lives and illnesses of every patient. Today, Engel's model is widely taught and practiced. Students and house officers are instructed in history-taking techniques that encourage patients to tell their "stories" as well as their medical complaints.

Having both practiced and taught internal medicine for more than two decades, I am convinced that the biopsychosocial approach is essential to the success of the physician-patient relationship. Unfortunately, the experiences of house officers in most teaching hos-

pitals these days make them dubious about the validity or relevance of Engel's model. The stories they hear from the patients who come to our teaching wards and clinics are so wrenching, or so incredible, or so freighted with the consequences of deprivation and depravity that they encumber rather than enhance doctor-patient interactions. The stories become mind-numbing rather than opening.

Let me give you an example. Table 1 lists topics posted recently for clinical conferences at Carolinas Medical Center. It is a curriculum as appropriate to a police academy as to a caring profession grounded in humanitarian ideals.

House officers whose senses and sensibilities are repeatedly buffeted by the exigent medical needs of poor, non-compliant, dysfunctional patients find it is less risky to the doctor-patient relationship to avoid patients' stories

rather than elicit them and then try to deal with the psychological and social desperation those stories reveal. It is frustrating enough to deal with the medical consequences of IV drug-related AIDS and endocarditis, alcoholic cirrhosis, and the like without shouldering the additional burden of knowing the details of patients' complicity in their medical problems. Here are two examples:

1) A third-year resident told me she was sure a patient with an obscure clinical problem was addicted to cocaine, though he denied it. "He's got my student

Table 1. Clinical conference topics

Internal Medicine:	The Cardiovascular Effects of Cocaine
Pediatrics:	The Impact of Violence on Children
Emergency Medicine:	Ballistics Domestic Violence Blunt Chest Trauma

and intern convinced he's never done drugs," she said. "Those poor innocents. I remember when I first started out—I believed patients who told me stories like that."

Now, from a more "mature" perspective, she had cast off her innocence, her credulity, and erected between herself and her patients a protective barrier of suspicion. She viewed a willingness to credit patients' stories as an impediment to reality-based medical care for disingenuous patients.

2) A second-year resident, when asked in the clinic why a young man, apparently healthy, was receiving Medicare benefits said, "I don't want to know."

"Why not?" I asked.

"I'm afraid I'll find out he's a deadbeat, and I won't like knowing that you and I are paying for his medical care."

Here again, the patient's story was viewed as a barrier rather than an asset to the clinical encounter. The resident avoided asking relevant questions lest he learn some "truth" about the patient that would clash with his own ethos and prejudice the clinical relationship.

What can be done to counter this kind of tacit obscurantism? How can the heart-hardening, compassion-fatiguing

reality of the stories doctors hear in their training be reconciled with the goals of the biopsychosocial model?

The logical first step is to seek greater socioeconomic diversity among the patients encountered by students and house staff. Although indigent patients will likely remain the core constituents of training programs, trainees need exposure to practice models other than hospital clinics and emergency rooms. Rotations on private inpatient services could be supplemented with tours in the offices of practitioners like Dr. Howell, whose patients are beset less by poverty and substance abuse than by biopsychosocial problems that resonate with the trainees' own experiences.

But it is not enough to vary the patient mix and thereby intimate to trainees (and to ourselves) that the biopsychosocial model applies only to "people like us," that the psychosocial dysfunction that leads to the biological wreckage of the down and out can be ignored. Such an approach would further alienate young physicians from many patients, and encourage rather than remedy class-based psychosocial nihilism.

One way to counter the erosive effect of such stories is to use clinical encounters as springboards for discussions

of economic, political, and public policy issues, ideally as part of a formal curriculum in biomedical ethics. As Virchow pointed out more than a century ago, "Medicine is a social science, and politics nothing more than medicine on a grand scale."³ Enriching the curriculum with stories that confirm the connections between social, economic, and medical pathology is a useful way to emphasize the physician's civic responsibility to participate in efforts to improve society.⁴ I am hopeful that integrating these issues into the medical curriculum will convince house officers that the biopsychosocial model will serve them well, both during their training and for the rest of their professional lives.

—William G. Porter, M.D.

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The Patient as the Focus of the Practice of Medicine

There is a profound but often unrecognized difference between the practice of medicine as taught in medical centers and as experienced by seasoned physicians. The academic or biomedical model is based on the belief that disease is the result of disordered pathways and that the task of a physician is to discover and, if possible, remedy the underlying defect. This approach is powerful in understanding disease; it is the construct that underlies most biomedical research. It has led us to exciting discoveries about the nature of many illnesses, and promises to

usher in a new era in which therapies can be tailored to specific diseases. Yet one of the central roles of the physician is often neglected and at times can be lost entirely in the biomedical model.

Medicine is a profoundly human science and art that is centered around the relationship between the physician and the patient. This relationship is both complex and intimate. It is within this relationship of mutual trust and respect that a patient can voice the fears and problems that led to the consultation, and it is within this relationship that physician and patient together explore and organize the patient's story.¹ The name given to the patient's problem—the diagnosis—is a method of understanding the patient's

problem, a legitimization of the problem, and a prognostication of the patient's likely course.²

As Dr. Howell describes, there are several effective ways for physicians to deepen their understanding of the therapeutic alliance. These include active listening to understand the patients' story, a method that can be enhanced by using longer interviews at times of crisis or impasse. In addition, a strong sense of one's own biases and weaknesses is helpful, as is continued reflection on one's interactions with patients, and what makes some relationships easy, some successful, and others difficult.³ These skills are not easy to master; like all art, they require practice. But they can be learned.⁴

Some medical education programs now include training in the doctor-patient relationship as a core part of their curriculum. At the Duke University School of Medicine, a relatively new program for first-year medical students has them interview "standardized patients." These are actors and actresses trained to portray patients. Students can repeatedly practice parts of an interview and receive feedback about relationships that were developed. Standardized patients provide a safe method of practicing developing rapport and learning a patient's story. Students learn about the doctor-patient

relationship and the biomedical model at the same time. Residency training programs in family medicine and in general internal medicine have long emphasized the biopsychosocial model and in interviewing and counseling skills. Yet training programs will never be sufficient; individual doctors must *choose* to develop the skills and sensitivity required to understand another person's story and gracefully guide the patient toward health. Dr. Howell exemplifies the self-aware and skillful physician who listens, understands, and heals.

—Lloyd Michener, M.D.

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The Importance Of Being an Artist

Both Dr. Howell and Dr. Porter have discussed Engel's biopsychosocial model¹ and its importance to the practice of medicine. Dr. Howell presents a fascinating summary of the psychosocial composition of his private practice and his formal problem patients. Dr. Porter's remarks deal with the difficulties that his house officers seem to have incorporating biopsychosocial aspects into their delivery of medical care due to the impression that delving into these issues may tend to "encumber rather than enhance patient-doctor interactions."

I find both of these observations very relevant to my duties at the Duke University Medical Center. Half of my time is spent like Dr. Howell, caring for a large panel of patients. Many of these patient are somatizers and have major psychosocial factors affecting their health. I, too, make "Balint agreements" with them, labeling their illnesses as "situational mood disturbance," "fatigue," "lassitude," or "dysfunctional sleeping pattern." Though I have not used the structured "long interview," and am not sure how, practically speaking, I could accommodate one into my clinic day, I am intrigued by Dr. Howell's success. Certainly these types of my patients seem to benefit

from frequent return visits during which "talking" is the main (and sometimes only) therapeutic intervention.

The other half of my time is spent developing curricula for, and teaching those curricula to, residents training in internal medicine because I serve as director of our primary care program. Since this program strives to train generalists,

"Doctors...prescribe
medicine of which they
know little, to cure
disease of which they
know less, in human
beings of which they
know nothing."

—Voltaire

we emphasize the biopsychosocial aspects of medicine compared to the traditional medical training program. It is a challenging endeavor. House staff (and unfortunately many faculty) are resistant to this biopsychosocial model and identify this "touchy-feely stuff" as not worthy of their time and effort. Regrettably, this "stuff" is often crucial for the effective care of the patient, and is, arguably, what separates a compassionate physician

practicing the art of medicine from a mere M.D. treating medical problems or investigating laboratory abnormalities.

I do not mean to imply that treating medical problems or evaluating laboratory abnormalities are trivial tasks. Training programs expend enormous sums of energy, money, and time exposing house staff to patients with illness, injury, and disease. The proposition is that this supervised and guided exposure will develop clinical competence. Subspecialty fellowship training may add more years of intensive, focused study on the problems of one diseased organ system or sometimes even a subsystem of that organ (e.g. cardiologists who are exclusively electrophysiologists). I do contend, however, that this descent down Engel's Systems Hierarchy² towards subspecialization emphasizes fixing the problems, not caring for patients.

Trainees resist embracing the biopsychosocial model because it does not conform with much of the way medical "science" is usually taught. Biopsychosocial subject matter is inherently difficult to describe or measure. It does not lend itself well to lists, tables, algorithms, or protocols. It does not follow tidy guidelines or rules of thumb. In short, it is perceived to be imprecise, "fuzzy," or less than "clean."

In addition, focusing only on "medi-

cal" problems appears to simplify the task at hand. The number of independent variables are fewer, the results are more predictable and, once obtained, are more easily reproduced. For the trainee this apparent simplification is very attractive and temporally rewarding as the results—positive or negative—are quickly available for decision-making purposes.

Though some problems may be simple, the patients who have them are rarely so. When a patient's complaints are not explained or when all the test results are unrevealing, a further investigation into biopsychosocial issues must be initiated. Even in patients where the scientific data are known, the "setting" in which they occur may have important

implications on the ultimate care of that patient. For instance, a positive pregnancy test may have markedly different ramifications on two medically identical patients depending on family issues, community issues, culture-subculture issues, and even society-nation/biosphere issues (ascending Engel's Systems Hierarchy). Helping these patients will intimately depend on all these factors.

Helping the patient is the ultimate goal of any clinical encounter. In some instances, this may be accomplished entirely by writing a prescription or treating a laboratory abnormality, but in many circumstances, it will not. Patients who have no measurable abnormality cannot be helped without incorporating a

biopsychosocial model into the clinical interaction. It is necessary to train house officers in the science of investigating and treating problems. It is even more important to help them learn the art of caring for patients. Our challenge as physicians is to emphasize both aspects equally and to instill similar attitudes in our trainees. If this can be done, there will be fewer "problem patients," although no fewer problems.

—Jeffrey G. Wong, M.D.

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Resident Training and the Biopsychosocial Model

What skills are essential to clinicians? This is a question that students of medicine and their teachers must address, often with little information about what practice is actually like. Reports from the "real world" are needed to inform medical school faculty and their trainees about the day-to-day realities of medical practice. Dr. Howell's description of one internist's practice is just such a report. His assessment of the needs of his patients and of the skills required to address them is, in fact, "pertinent to the issues" of our time, particularly the mandate to train more generalist physicians.

From Dr. Howell we learn that caring for the psychosocial needs of patients is central to a doctor's work, but that the skills requisite to this task are often neglected in a doctor's training. I was struck that Dr. Howell needed to teach himself the techniques of psychosocial data gathering, analysis, and intervention *after* he entered practice rather than receiving instruction during his residency. In keeping with the principles of adult education, the motivation to learn stemmed from the

clinical problems he faced in his practice. He needed new skills when he found the biomedical model insufficient to make sense of his patient's complaints. Although certainly a tribute to this doctor's independent and self-directed learning, the implications for residency training are less than flattering. One of the greatest compliments paid to a doctor is that he or she is "well trained." Dr. Howell's practice is evidence that a medical education that neglects psychosocial skills can no longer be considered adequate.

In his response to Dr. Howell's paper, Dr. Porter agrees with the validity of the biopsychosocial model but raises important issues about the darker side of residency training on the wards and in the clinics of our teaching hospitals. There is no doubt that residents can be overwhelmed by the stories of neglect and abuse they confront every day. However, these stories support rather than invalidate the biopsychosocial model for understanding illness and the care of patients. The vignettes Dr. Porter presents suggest a wealth of teaching points. The problem with medical education is that these points are often neglected in case discussions and supervision just when residents most need the direction and support of their

mentors. On rounds most attending physicians stick to what they know best, the biomedical, and leave residents to fend for themselves with difficult patients and their families. The message, intended or not, is that psychosocial care is nice if you have the time, but it is certainly not the coin of the realm. No wonder our residents feel overwhelmed in the care of patients. This is a response to confronting complex tasks without an organized approach, without tools and without help. It is not difficult to imagine that residents turn to subspecialty practice in order to "escape" problems that make them feel vulnerable and inadequate.

Changes are needed in our approach to medical education if we hope to attract trainees into primary care careers and provide them with the skills they need to be clinically effective and personally fulfilled. Variation in patient mix through meaningful rotations outside the teaching hospital is an important step; a month working in a practice like Dr. Howell's might critically influence a resident's career plans. Residency programs must provide these opportunities. Furthermore, the provision of service to indigent populations should not be the decisive determinant of the training experience.

We must also provide instruction and feedback in the core clinical skills of the medical interview and doctor-patient relationship. These skills can be taught and

can prepare young physicians to develop more sophisticated skills in managing psychosocial problems. Then our residents may find, like Dr. Howell, that a

career in primary care can be intellectually and personally satisfying. And, their patients will thank them for listening.

—Peter R. Lichstein, M.D.

My Clinical Odyssey

Dr. Howell's description of the content of his practice emphasizes that fact that long-term relationships can be established and can facilitate the diagnostic capabilities of a primary care physician. The seed for my own interest and concern for patients as whole people was planted during my career as a general medical officer in the Navy from 1971 to 1973. I had finished medical school, a year of rotating internship and one year of internal medicine residency. I assumed I was well-equipped to handle practice in the military, caring for dependents as well as naval personnel. I remember struggling with diagnosis and treatment of symptoms that arose not from altered structure or organs and tissues but from altered physiology and the perception of dependents whose spouses were away under wartime conditions. Librax did little to ease the pains of irritable bowel syndrome magnified by stress in the young mothers living essentially as single parents. It was then I learned that a concerned expression, a listening ear, and supportive words provided more comfort than all of the medications I knew about.

I had had no instruction in the art of listening or in the art of pulling together elements of my patients' personal lives or in how these could affect the perceptions of functional signals from the body. I was ill-equipped to be in primary care. I began my quest for appropriate education, one not found in most university medical centers, in the early '70s. After a year of an Ambulatory and Community Medicine residency in San Francisco, I was pointed toward Rochester, New York, by colleagues and mentors who knew of my interest in whole person or psychosomatic medicine. I finished my residency at Rochester, and then, along with Art Schmale and Mack Lipkin, Jr., became a disciple, so to speak, of George Engel and

his staff during a one-year fellowship in Medicine and Psychiatry. We learned Dr. Engel's non-intrusive way of obtaining a personalized yet scientific data base. He uses open-ended questions to allow patients to express themselves more. Listening intently and repeating words selected from the patient's story has the automatic effect of encouraging the patient to expand on the repeated words. This simple verbal gesture encourages them to follow their own linkage of symptoms to events, people, and experiences. Not only did we get more information in less time but, by allowing patients to tell their own stories, we witnessed the connection to people, events, issues, and feelings—a richer experience than the "natural history" of a heart attack, abdominal pain, or phlebitis. Diseases (pathologic entities) became illnesses (altered states of health perceived and experienced by real people). We could, therefore, respond more appropriately to the suffering person. Dr. Engel not only gave us the science of the biopsychosocial model, but also the art and craft of obtaining the data. Each encounter becomes unique if one can minimize telephone interruptions, billing questions, and the learning of new evaluation/management criteria of the current charge system.

I have taught Dr. Engel's approach to second-year UNC medical students who take a physical diagnosis clerkship at Wake Medical Center. It is a real joy to introduce this sound but thoughtful approach to history-taking to these students. It is a joy to watch them establish their first relationships with patients. They reflect humane concern and a depth of compassion that is rarely matched by older students and most older physicians.

I wonder, though, what becomes of this compassion and curiosity with time. I see these students again in their third-year medicine clerkships, their fourth-

year acting intern rotations, and I see them as interns and residents. A change takes place over these subsequent years that I cannot easily describe. I think what I see is an increasing concern for biomedical diagnosis and therapeutics and a decrease in attention to the personal attributes and the personal stories of each patient. Not only is some of the human touch lost but so are some of the data that allow individualized and holistic care. Post-graduate training emphasizes accuracy in diagnosis, good judgment in therapeutics, and broad knowledge of medical literature, but the humanistic element of patient care often takes a back seat. How can we modify training so that students can become physicians who maintain confidence in their diagnostic skills and their therapeutic decisions and also become artful, caring persons?

Beyond medical students, though, I am more troubled by the changes that I see among some of my colleagues. One of my patients recently underwent spinal fusion in an effort to treat chronic low back pain. But two to three months after surgery she had no improvement; she complained about her inability to work and to pay physician's bills (\$12,000 in surgeon's fees, excluding hospital services). She stated that the operation was broken down into four procedures with separate charges for each. Her insurance company paid \$8,000; the surgeon is being reimbursed for the remaining \$4,000 at \$50 a month by a woman who is disabled and living on pension alone. Where is the concern for our profession? Medicine's challenge is to choose, encourage, and develop students who want to stay human and who value the relationship, value the science, and the art Dr. Howell describes. My hat is off to Dr. Howell for describing the process of a complete physician.

—Edward B. Yellig, M.D.

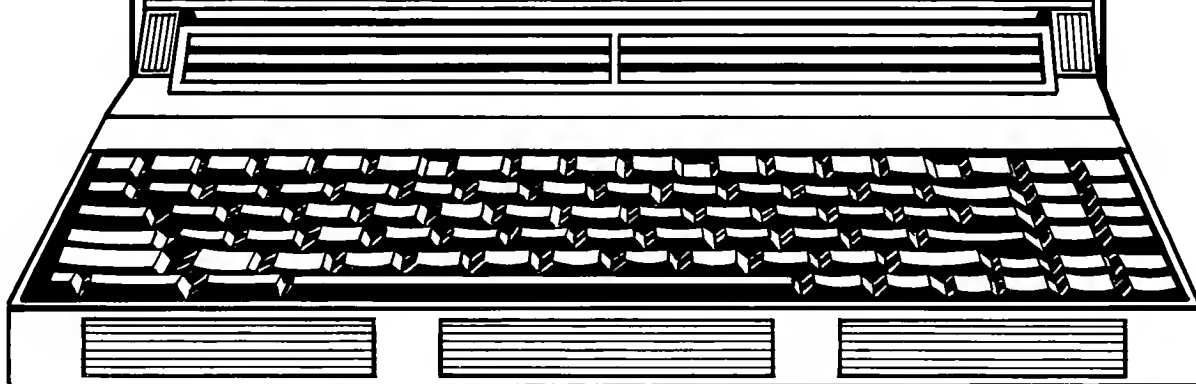
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Prolonged administration of VICODIN/VICODIN ES Tablets may produce constipation. **Genitourinary System:** Urteral spasm, spasm of vesical sphincters and urinary retention have been reported. **Respiratory Depression:** Hydrocodone bitartrate may produce dose-related respiratory depression by acting directly on the brain stem respiratory center. Hydrocodone also affects the center that controls respiratory rhythm, and may produce irregular and periodic breathing. If significant respiratory depression occurs, it may be antagonized by the use of naloxone hydrochloride. Apply other supportive measures when indicated. **DRUG ABUSE AND DEPENDENCE:** VICODIN/VICODIN ES Tablets are subject to the Federal Controlled Substance Act (Schedule III). 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Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion. **Hydrocodone Signs and Symptoms:** Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdose, apnea, circulatory collapse, cardiac arrest and death may occur.

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A Response to:

"A Woman With Too Much Facial Hair"

Editor's Note: Dr. Warner M. Burch, Jr., of the Division of Endocrinology, Department of Medicine, Duke University Medical Center, Durham, submitted the following response to Dr. Doris Iarovici and Dr. Francis A. Neelon's article in the August issue titled, "A Woman With Too Much Facial Hair: Evaluating the Possibility of Attenuated 21-Hydroxylase Deficiency in Hirsutism," (NC Med J 1992;53:401-403).

The article in the August issue, "A Woman With Too Much Facial Hair" points to the difficulties in diagnosing attenuated 21-hydroxylase deficiency. Drs. Iarovici and Neelon ably show that test results when erroneously recorded lead to confusion and misdiagnosis. What was not stated outright was how to interpret the numbers obtained. The diagnosis of attenuated 21-hydroxylase deficiency (late-onset variant of congenital adrenal hyperplasia) must be made biochemically since it is clinically indistinguishable from simple hirsutism or polycystic ovarian syndrome.

Elevated serum 17-hydroxyprogesterone (17-OHP) levels define the disorder. Normal women have serum 17-OHP less than 2 ng/mL (<6 nmol/L) in the morning during first week after menses; in fact, the mean is usually less than 1 ng/mL. Slightly higher levels (up to 2.5 ng/mL) occur in the luteal phase of the menstrual cycle. Levels of 17-OHP obtained 30 to 60 minutes after cosyntropin (ACTH) stimulation (0.25 mg IV or IM), rarely rise above 3.5 ng/mL (10.5 nmol/L) in normal women. In the severe (homozygous) form of 21-hydroxylase deficiency, basal or non-stimulated 17-OHP levels are above 10 ng/mL (30 nmol/L). It is usually not a diagnostic problem to recognize infant females with severe 21-hydroxylase deficiency since they usually exhibit ambiguous genitalia.

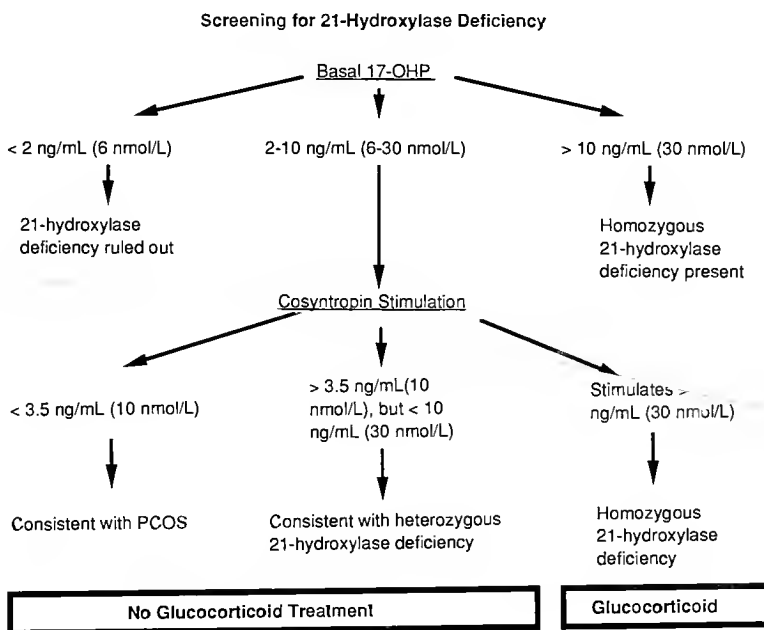
However, for unknown reasons the attenuated variety of 21-hydroxylase deficiency does not cause changes in infancy but may present with hirsutism years later. Mildly elevated 17-OHP be-

tween 2 and 10 ng/mL (6-30 nmol/L) can be seen in both homozygous and heterozygous attenuated 21-hydroxylase deficiency (the latter is not associated with hirsutism) as well as in polycystic ovary syndrome. Cosyntropin stimulation distinguishes these conditions; 17-OHP rises above 10 ng/mL (30 nmol/L) in homozygous attenuated 21-hydroxylase deficiency. The criteria for diagnosis rest on the absolute magnitude of response rather than the relative increase over baseline. I have found the accompanying algorithm (below) helpful.

The true incidence of attenuated 17-hydroxylase deficiency is unknown. My

experience reflects those of Chetkowski et al (J Clin Endocrinol Metab 1984;58:595-8) in which this disorder accounts for about 1% of hirsute women. The message is: "Attenuated 21-hydroxylase is a rare cause of hirsutism."

I am reluctant to place hirsute women on glucocorticoids unless congenital adrenal hyperplasia is confirmed. Prednisone, for example, is difficult to adjust and monitor and the associated weight gain is a "no-no" for most patients. It is best to make sure the criteria are well established before submitting women to such therapy. I pass this along as a fellow sailor on an uncharted sea. □



Responses to:

"Youth and Tobacco"

RJR's Medical Director and Two Family Physicians Discuss the Issue of Smoking Among Youth

Editor's Note: Dr. Robert G. Fletcher, medical director of the R.J. Reynolds Tobacco Co. in Winston-Salem, submitted the following letter to the *Journal* in response to Dr. Adam O. Goldstein's August Health Watch article titled, "Youth and Tobacco: Addiction and Death," (NC Med J 1992;53:411-414). Samples of RJR brochures and other materials designed to reduce smoking among youth accompanied the letter. Because of the nature of Dr. Fletcher's remarks and the research he cites, we invited Dr. Goldstein and Dr. Joseph R. DiFranza to respond. Dr. Goldstein is a clinical instructor and primary care researcher in the Department of Family Medicine at the University of North Carolina at Chapel Hill and is a member of the North Carolina Medical Society's Tobacco Control Task Force. Dr. DiFranza is a member of the faculty of the Department of Family and Community Medicine at the University of Massachusetts at Fitchburg, Mass.

Dr. Fletcher's Letter:

As a practicing physician in occupational medicine and environmental health, a member of the North Carolina Medical Society, and an employee of R.J. Reynolds Tobacco Co., I feel compelled to express my extreme disappointment in Dr. Adam Goldstein's Health Watch article "Youth and Tobacco: Addiction and Death." I strongly share Dr. Goldstein's belief that children should not smoke, as does my company. I do not, however, share his apparent belief that it is acceptable to disregard or distort facts to make his point. Nor do I believe he is serving the Medical Society by presenting members' patients with false and unsubstantiated information.

To cite just some examples: Dr. Goldstein claims that the tobacco industry spends billions of money promoting its products to youth. This is blatantly false. None of Reynolds Tobacco's product advertising or promotions are directed toward anyone under legal smoking age. To the contrary, our company devotes significant resources to developing and distributing youth-directed materials de-

signed to reduce the incidence of smoking among youth.

Dr. Goldstein claims that 90% of smokers start before age 21. The legal age to smoke in North Carolina is 18, not 21. Moreover, the 1989 Surgeon General's Report indicated that the mean age of smoking initiation is about 18.

Dr. Goldstein points out that children as young as 3 are aware of advertising. A child's awareness has nothing to do with whether that child engages in a particular activity. Three-year-olds are aware of many products that they have no desire or ability to use. In addition, studies have consistently shown that young children have very negative attitudes about smoking.

Dr. Goldstein gives the false impression that smoking is on the rise among youth. In fact, according to the Department of Health and Human Services, youth smoking in the United States has declined significantly—by 35%—during the past 15 years. More importantly, during the same period, children's disapproval of smoking has steadily grown.

Dr. Goldstein rightfully acknowledges that peer pressure prompts chil-

dren to start smoking. However, his claim that "peer pressure itself is often initiated and sustained by the tobacco industry" is unsubstantiated conjecture. Countries where tobacco advertising and promotion are prohibited have problems with youth smoking too. In addition, numerous studies, including one by the World Health Organization, show that advertising has little, if any, effect on the decision to start smoking. Clearly, one cannot blame peer pressure on advertising.

Perhaps the more egregious statement Dr. Goldstein makes is his claim that RJR's advertising for Camel cigarettes "has proven to be very successful in addicting many North Carolina youths to use Camel cigarettes." To back this claim, he says, "Research reported in the *Journal of the American Medical Association* showed that Old Joe was as well recognized by 6-year-old students as was a picture of Mickey Mouse, and that RJR was as effective as Walt Disney in reaching such young children."

Dr. Goldstein co-authored the research he is citing and the claim he makes is distorted by selectively reporting data from that study and from another study

that appeared in *JAMA*. Neither of these studies showed that advertising influences smoking initiation, and neither was conducted in North Carolina. These studies do not support his unfounded contention that Camel advertising causes North Carolina youths to start smoking.

Dr. Goldstein's claim that Camel ads are prompting children to smoke is based on the response of 21 out of 23 Atlanta 6-year-olds who matched a picture of Joe Camel with a picture of a cigarette. He and his co-authors focused on 6-year-olds because that was the only age group in the study that had a high recognition rate. The fact is, 229 children ages 3 to 6 participated in that study, and results show that almost all of the children recognized the Disney logo while only about half recognized Joe Camel. The study also found that more children recognized Chevrolet and Ford—and the

logos for seven other categories—than recognized Camel.

In another *JAMA* article in the same issue, Dr. Joseph DiFranza and his colleagues wrote: "Our study provides further evidence that tobacco advertising promotes and maintains nicotine addiction among children and adolescents." But a few months later Dr. DiFranza told a *Winston-Salem Journal* reporter, "None of these studies were designed to show that these Camel ads increased smoking among kids."

Documents obtained from Dr. DiFranza reveal that when he started collecting data, he found that Camel ads appealed more to adults aged 18 to 24 than to those under 18. Based on those results, Dr. DiFranza wrote, "It would appear that we have just disproved our theory that the ads appeal more to kids than to adults."

His research showed that regardless of how recognizable the Camel campaign was, 98% of the non-smoking youths he surveyed considered smoking unpopular and unattractive. Out of more than 740 non-smoking youths, Dr. DiFranza found only three non-smoking students who said they intended to smoke during the next year.

Dr. Goldstein's attack on Reynolds Tobacco ignores the fact that even the Centers for Disease Control acknowledges that Camel is a distant third brand choice among underage smokers. Perhaps he believes that there is nothing wrong with distorting the facts when it serves what he considers to be a greater good. I hope, and suspect, that I am not alone among Medical Society members when I contend that there is no excuse for providing patients with personal opinion disguised as established fact. □

Dr. Goldstein Responds:

Despite being a physician, Dr. Fletcher resorts to partial truths and purposeful neglect in an attempt to justify the active marketing of products that kill more than 400,000 people in America and 2 million people worldwide every year. His claims that I "distort" scientific facts seems perverse since the industry he represents has never publicly acknowledged the more than 50,000 articles that link tobacco addiction and carcinogens to disease. Dr. Fletcher and I agree on only one point: It is "not acceptable to disregard or distort facts to make a point."

For the record, I stand behind every word of my August 1992 *Health Watch* article on protecting our youth from tobacco. More than 1 million people (mostly teenagers) must take up smoking each year to replace those smokers who quit or die from tobacco-related diseases.¹ Dr. Fletcher seems to be unaware of, to have misinterpreted, or to have deliberately misquoted the research on youth experimentation with tobacco. References supporting points I made in my article,

including the effects of tobacco advertising on adolescent smoking, are readily available from reliable sources.¹⁻⁷

Adolescents usually smoke one of just three brands of cigarettes: Marlboro, Newport, and Camel.⁷ In 1989, just as RJR's Old Joe campaign was getting into full swing, Camels were preferred by less than 6% of Southern teenagers. By 1991, Camel cigarettes were the preferred brand of 35% of 9th-grade smokers in Raleigh⁷ and of 33% of high school student smokers nationwide.⁶ By contrast only 4% of all adults prefer Camels. The evidence is clear that the "Old Joe" character is designed to appeal to kids, and the campaign has worked brilliantly! Adults do not rush out to get cartoon Camel Cash, cartoon Camel playing cards, coolers, T-shirts, caps, boxer shorts, and more.

Recent studies show unequivocally that the tobacco industry knows how to devise campaigns to reach children, even as young as three years old.^{3,6,7} In North Carolina more than 94% of 8th graders know "Old Joe" just from his picture, 55% associate a cowboy with an ad for Marlboro cigarettes, and more than 40%

of boys associate a picture of a Native American with Red Man chewing tobacco.⁹ The tobacco industry's highly publicized campaigns to dissuade youths from tobacco are specious, have had no impact on reducing adolescent consumption of tobacco products, and actually increase tobacco consumption.^{10,11} Virtually all public health experts, including the Surgeon General of the United States, the National Cancer Institute, the American Heart Association, the American Lung Association, and the American Cancer Society agree that tobacco advertising and promotion are major causes of adolescent and adult tobacco use.

Dr. Fletcher is worried about a potential conflict of interest because I am a co-author of a lead article on tobacco and children (in *JAMA*, a peer-reviewed, premier scientific medical journal), and I also wrote a recent *Health Watch* article on tobacco use by adolescents (requested by the Medical Society). I am a non-smoker, own no tobacco stock or tobacco farms, have never consulted for the tobacco industry, have no personal finan-

cial gain from doing tobacco-related research, have never fabricated or distorted science for my own interests, do not enjoy making a living off other peoples' suffering, won't lose my job if I tell the truth, believe that tobacco addiction is bad for children and adults, and counsel all my patients to quit smoking. Can Dr. Fletcher or RJR make similar responses?

If Dr. Fletcher and the R.J. Reynolds Tobacco Co. truly do not want children (or adults) to smoke cigarettes and use smokeless tobacco perhaps they can convince the citizens of North Carolina and the members of the North Carolina Medical Society by:

- 1) Admitting that tobacco use causes lung cancer, heart disease, emphysema, and is a very addictive habit;
- 2) Apologizing to every family of the now more than 11,000 North Carolinians who die each year from tobacco-related diseases;
- 3) Paying expenses for every tobacco addicted man, woman, and child who wants and needs help in quitting;
- 4) Eliminating all marketing, promotional, and sponsorship practices that appeal to children (such as cartoon characters and auto races);

- 5) Spending one dollar on tobacco use prevention for every dollar spent on promotion;
- 6) Supporting an increased legal purchase age for tobacco products equal to that for alcohol, and supporting efforts at strict enforcement and penalties for noncompliance;
- 7) Opening the RJR marketing files of the past 25 years to public scrutiny.

Since neither Dr. Fletcher nor RJR want kids to smoke, can I safely assume that RJR will not be handing out free cigarettes, sponsoring "rides," or having a "Winston" souvenir booth at this year's NC State Fair? Dr. Fletcher's disappointment notwithstanding, until RJR, Philip Morris, and the other tobacco companies begin corrective actions, I, as a board-certified family physician and an active member of the Medical Society, will continue to reject corporate profits, greed, and death in favor of my patients' health. □

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Dr. DiFranza Responds:

Dr. Fletcher, on behalf of the R.J. Reynolds Tobacco Company, has disregarded and distorted the facts regarding my research into the effects its cartoon advertisements have on children's smoking behavior. Although I have informed them under oath that the tiny pilot test I conducted is not (and was never intended to be) a scientifically valid study, they continue to quote from it inappropriately while ignoring the valid, peer-reviewed, and published results of our final study.¹ This is dishonest.

Prior to R.J. Reynolds' use of cartoons to advertise Camel cigarettes only 0.5% of adolescent smokers smoked Camels.¹ Now three published studies

place Camel's underage market share at 32.8% (both sexes), 29.7% (both sexes), and 24.5% and 21.7% for boys and girls respectively.¹⁻³

The use of cartoons to advertise Camels has clearly resulted in a windfall of new sales of Camels to children. R.J. Reynolds has received nearly universal condemnation for its use of cartoons to advertise Camels. I believe that if R.J. Reynolds was truly upset about receiving hundreds of millions of dollars in profits from the illegal sale of Camel cigarettes to adolescents it would discontinue using cartoon advertising. Despite scathing criticism, and despite R.J. Reynolds' stated concerns about children, the company has chosen instead to expand its Camel cartoon promotional efforts.

Readers can make their own judgments as to the motivations of the R.J. Reynolds Company. □

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Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalamic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon® is indicated as a sympatholytic and mydriatic. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.^{1,2} Also dizziness, headache, skin flushing reported when used orally.^{1,3}

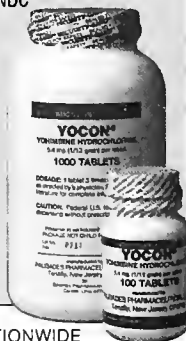
Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

How Supplied: Oral tablets of Yocon® 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.

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Text (including Letters to the Editor) should be typed with one-inch margins and double-spaced. Title page should include address, and phone and fax numbers of the corresponding author. Submit two copies or a cover letter and a 3 1/2- or 5 1/4-inch computer disc with text written in MS DOS compatible format (WordPerfect, Microsoft Word, Displaywrite, or ASCII).

Submit illustrations, in duplicate, in the form of color 35mm slides or glossy photographs, or as black-and-white glossy photographs. Label them with author's name, note their position in the text, and indicate image orientation, if necessary. *Do not write on the backs of prints.* Type legends separately. Tables should be typed, double-spaced, one to a page. Tables must have titles and consecutive Arabic numbers.

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Was Hercules a Stable Person?

Astemizole Overdose

Ronald B. Mack, M.D.

In Greek mythology there were men known as Heroes. These dudes were half god and half man and resulted from a connubial encounter between a god and a comely human maiden—truly slap and tickle at its finest. The greatest of all the heroes was Hercules, the son of Jupiter (father of the gods) and the princess of Thebes.¹

Our Hero had enemies and one of the meanest was Juno, Jupiter's sister. Juno caused Hercules to be pazzo (crazy), and in a fit of madness killed his own children. Hercules was given Prozac and recovered but he wanted to expiate his guilt and asked the oracle at Delphi for advice (at \$110 an hour). The oracle suggested that Hercules serve the King of Mycenae. The King gave the unfortunate hero difficult tasks to perform, one for each of 12 years—known as the Twelve Labors of Hercules.²

The Fifth Labor was to clean the stable of Augeas. The stable held 3,000 cattle and had not been cleaned for 30 years. Hercules promised to clean them in one day if the King would get him some antihistamines for his hay fever. The King got him some diphenhydramine and our Hero took a Herculean dose, fell asleep, and did not finish the Labor in one day as promised.

Until recently if one needed an antihistamine most of your choices, depend-

ing on the dose, could cause drowsiness, dizziness, weakness, confusion, dry mouth, blurred vision, diplopia, and so on, making everyday chores a Herculean labor. Could he have been given an antihistamine that was less sedating? Read on and decide for yourself.

Classifying Antihistamines

The first antihistamine for clinical use was developed by B.N. Halpern in 1943.^{3,4} Today there are more than 60 oral antihistamines available either alone or in combination with a decongestant or other ingredients. They are present in "cold" remedies, anti-allergy preparations, "sinus" remedies, hypnotics, anti-nausea agents, pre-surgery medications, motion sickness remedies, and anti-Parkinsonian drugs.⁵

Antihistamines are chemically known as H1-receptor antagonists or H1 blockers.⁶ In terms of pharmacological action most H1-blockers share the following characteristics: they inhibit most smooth muscle response to histamine, they strongly antagonize the actions of histamine, resulting in increased capillary permeability and the formation of wheals and edema, and they block histamine during allergic reactions, including anaphylaxis. This group of drugs can be divided into several classes,⁶ e.g. ethanolamines (e.g. diphenhydramine), ethylenediamines (e.g. pyribenzamine),

alkylamines (e.g. chlorpheniramine), piperazines (e.g. hydroxyzine), phenothiazines (e.g. promethazine) and the newest group, the piperadines (e.g. terfenadine [Seldane®] and astemizole [Hismanal®]). It is this latter class of antihistamines that concerns us today, especially astemizole.

The newer H1 antagonists, i.e., the piperadines, do not penetrate the central nervous system, allegedly, and are metabolized to compounds that are active H1 antagonists.⁶ One of the major marketing tools of the companies that sell these products is that these compounds are non-sedating, and, indeed this seems to be true; these remedies have become very popular. Astemizole has peak plasma levels reached at one to four hours post-ingestion.⁷ Ingestion of food, contemporaneously, increases the time required to achieve peak concentration and significantly decreases bioavailability. The protein binding of this drug is 96.7% and the volume of distribution is 250 L/kg, making this chemical a very poor candidate for extracorporeal removal in patients who seriously overdose on this drug.

Clinically there are two other major advantages to therapeutic doses of astemizole, i.e., the drug does not appear to cross the blood-brain barrier and does not possess anti-cholinergic properties, as do many of the other classes of antihistamines.⁸ The half-life is quite long; 20 to 24 hours, in experimental studies. Sustained action is considered another advantage of this product.

From the Department of Pediatrics, Bowman Gray School of Medicine, Wake Forest University, Winston-Salem 27103.

Determining Dosage

If astemizole is so wonderful why is this paper being written? Is it the answer to a Hero's prayer? With therapeutic dosage you have some assurance of therapeutic efficacy, lack of drowsiness, or impairment of driving ability. In overdose, astemizole can be wicked indeed, producing CNS depression but more frighteningly, cardiac arrhythmias, especially those of the ventricular persuasion.^{5,7,9,10} Ingestion of 200 mg has produced mild drowsiness in one adult patient and severe ventricular arrhythmia in another.⁷ Ventricular arrhythmias have occurred in children ingesting six to eight mg/kg.¹⁰

The pediatric literature acknowledges that a dose-response relationship may exist for cardiotoxicity secondary to an astemizole ingestion but data are insufficient to determine a "safe" ingested dose below which cardiac effects do not occur. One pediatric patient, recently described, ingested only 1.7 mg/kg and suffered severe dysrhythmias.⁹ This medication is usually dispensed in 10 mg doses, and the usual adult dose is 10 mg once a day, on an empty stomach.⁷ Children 6 to 12 years old can be offered a 5 mg tablet daily and children less than 6 years old 0.2 mg/kg daily. If the average two-year-old is approximately 13 kg, and severe arrhythmias have been reported with as little as 6 mg/kg, or less, then a handful of 10 mg pills can be devastating indeed, if ingested by a small child.

Astemizole overdose in children can induce very frightening cardiotoxic effects characterized by prolonged QT interval, atrioventricular block, and ven-

"Astemizole overdose
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atrioventricular block,
and ventricular
arrhythmias."^{9,14}

tricular arrhythmias.^{9,14} The pathologic reason for this toxicity is unknown but apparently, H₁ receptors are found in the heart and may modulate atrioventricular conduction.¹¹ Blockade of these receptors can produce prolongation of the QT interval and predispose to reentry of cardiac conduction resulting in torsades de pointes or ventricular tachycardia. Torsade has a bizarre orientation of the QRS complexes in association with a prolonged QT interval and poor prognosis.¹² Overdose can also result in sedation and generalized seizures, but the cardiac events appear to be the most frightening.

Managing an Overdose

What is a clinician to do when faced with the problem of an astemizole ingestion by a child? The prospect of severe consequences from the ingestion of only a few pills should prompt the doctor to provide emergency evaluation, induction of emesis with ipecac, if the patient is at home, is not obtunded or convulsing, and is

within 30 minutes of ingestion.^{7,9} If the patient is in the ED do not administer ipecac but do administer activated charcoal and one dose of a saline cathartic or sorbitol. Some authorities recommend multiple dose charcoal therapy, i.e. every four hours, until the QTc is normal.¹¹

Similar cardiotoxic events have been described in terfenadine overdose (Seldane®) necessitating similar management of such cases. During the month of July 1992, Marion Merrell Dow sent us all a warning about their product, Seldane®, and cautioned the prescriber to avoid prescribing this drug in patients co-ingesting ketoconazole or erythromycin or who have hepatic dysfunction. The conclusion is simple—all drugs are capable of side effects, and you can get too much of a good thing.¹³

Mythological Musings

My favorite story about Hercules concerns his 18th birthday;¹ can you remember yours? He perceived that two women were coming his way, both comely. One breaks away and rushes to his side. She invites him to follow her and have an easy and pleasant life, no hard work, no dangers, only enjoyment; her name, she said, was Pleasure. The second young beauty then said, "follow me and you will accomplish great deeds but you will have to work hard and must serve the gods;" she said her name was Virtue. Our Hero chose to follow Virtue. Did he make the correct choice? I wish I had those options before me now, don't you, even for a little while? □

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Official Call House of Delegates

House of Delegates Meetings Scheduled

Notice to:

Delegates, Alternate Delegates, and Officials of the North Carolina Medical Society, component medical societies, and specialty societies.

Sessions of the House of Delegates will convene in the Grand Ballroom of the Pinehurst Hotel, Pinehurst, North Carolina, at the following times:

Friday, November 6, 1992 - 8:30 a.m. - Opening Session
Sunday, November 8, 1992 - 9:00 a.m. - Second Session

A member of the Credentials Committee will be present at the Meeting Registration Desk in the Exhibit Hall on Thursday, November 5, 1992, from 3:00 p.m. to 5:00 p.m., and Friday, November 6, 1992, from 8:00 a.m. to 9:00 a.m. to certify Delegates. Delegates must bring their Credential Cards for presentation at the Registration Desk. Delegates must wear their badges to be seated in the House of Delegates.

Reference Committee Hearings

**Reference Committee hearings are scheduled
to begin Friday, November 6, 1992, at 2:00 p.m.**

John T. Dees, MD, President
F. Maxton Mauney, Jr., MD, President-Elect
John A. Fagg, MD, Speaker
Alfred L. Ferguson, MD, Vice-Speaker
Carolyn R. Ferree, MD, Secretary-Treasurer
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Two Fewer Stars in Our Firmament

Francis A. Neelon, M.D., Editor

Mebane Holloman Burgwyn

From a certain spot on that thin, geographically vertical slip of sand called Hatteras Island, just above the elbow where the East-West run turns North-South, I have, when the climatic and seasonal conditions were right, seen a remarkable sight. At dusk, as the sun sits on the horizon beyond the sound, it assumes a bell shape. No longer round, the distorted disk seems to hover for a moment disconnected from the long line of sea or cloud, red as a ripe pear and luminous. Then, with a rapidity that seems almost palpable, the sun shrinks and turns. Puff! it is gone!

I thought of that moment last August when I was with Mebane Burgwyn on what, it would turn out, was her last day with us. Readers of the *Journal* will remember how her filigreed prose graced our pages as she herself had graced us with her presence. She had vaulted a number of high hurdles over the past eight years, especially those surrounding the diagnosis and treatment of the lymphoma that she recounted so winningly in the *Journal* in "Medical Mystery and the Whistle Blower" (NC Med J 1984;45:567-575).

I was pleased that she continued to think of me as her doctor, even when I had to retire into the medical shadows to make room for the real experts. And they did well by her. Her strength came back, and she returned to writing, to painting, to life. When the tornado of 1988 skipped across

eastern North Carolina and struck the farm that she and her husband, John, kept near Occoneechee Neck, she photographed the trees festooned with ruined cotton and she wrote for us again, about the tribulations that the storm wreaked amongst her chickens and her people ("Tornado Trauma down on the Farm," NC Med J 1990;51:97-100). That deceptively simple story brought Chaucer to my mind when I read it and I think she was pleased when I told her so. She was present when a group of us discussed that story together and she laughed with us when Pat Kenan captured its essence by asking, "What do roosters want, anyhow?"

What indeed! To scratch in the dirt, to have our brood safely about us, to crow at times, to strut a little. Mebane Burgwyn knew about how good those things are and she held them up for us to see, too. Then, last year when she could no longer work her garden without getting short of breath, she came to see me. There was fluid in the left hemithorax; unexpectedly the lymphoma was back. This time there was no miraculous recovery although she and her doctors fought mightily for it. Fought until the last day or two when the end was clear and she submitted. Then, in a puff, Mebane Burgwyn was gone. Now we who knew her remember aloud her courage and her spark and how she subscribed to and read this journal and not once but twice gave life to the motto on our cover: "*North Carolina Medical Journal*—for doctors and their patients." □

Charles Woodrow Styron, M.D.

Charles W. Styron, faithful member of the North Carolina Medical Society since 1946 and President in 1972, served on the Editorial Board of the *North Carolina Medical Journal* since 1960 and as Chairman of that Board from 1975 until his death on August 22, 1992. A native of New Bern, Dr. Styron graduated from North Carolina State College and Duke University Medical School. After a residency in Internal Medicine at the Boston City Hospital and a fellowship at the Joslin Clinic in Boston, he served four years in the wartime Navy. After his discharge in 1946, he established a practice of Internal Medicine and Diabetology in Raleigh and it was in that role that I first came to know him 25 years ago—when he came to Durham as a volunteer Preceptor in the Diabetes Clinic at Duke Hospital. (An institution to which I had recently come from Boston and the Boston City Hospital!)

My real acquaintance with Charlie Styron, though, began in 1983. That was the year in which he mutually

convinced Eugene A. Stead, Jr. and the Medical Society that the appointment of Dr. Stead as Editor of the *Journal* was the only solution to its impending dissolution. I inveigled Dr. Stead to appoint me as Associate Editor and thus I began 10 years of watching Stead and Styron in action as they (successfully) resuscitated the *Journal*. Like the man who could not describe *Art* but who could recognize it when he saw it, Charlie Styron saw what goals the *Journal* might achieve and he pushed us relentlessly to attain them.

After Dr. Stead's retirement in 1991, Charlie Styron came again to the rescue of the *Journal* by resisting those who wanted to subvert his vision of what this state medical journal is and should be. It is, then, no exaggeration to say that the *Journal* twice owes its present existence to the tenacity, the dedicated leadership, the consistent and unflagging determination of Charlie Styron. We are sad that he is gone, but glad that he was with us. He set the example for us all of what it means to live out the motto of his native North Carolina: *Esse quam videre*. □

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Health Watch

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Prescription Drug Use

PRESCRIPTION MEDICATION—WHAT YOU NEED TO KNOW

Today's medicines are powerful chemicals. They're used to treat disease, heal injuries and relieve pain. Used properly, modern medications can treat everything from headaches to heart disease. Used carelessly, medicines can cause unexpected danger. Instead of relieving symptoms, they can cause poisoning and, in some cases, death. Let's take a look at prescription medication use as it relates to different groups of people.

Medicine Issues for Women

During her life, a woman may have special issues to consider in connection with medicines.

Oral Contraceptives

Birth control pills have been around a long time. Talk with your doctor about their risks and benefits in relation to your health. Special aspects of birth control pills to understand:

- If you smoke, are overweight or have high blood pressure, heart disease or cancer, you probably should not take the pill. The pill is widely reported as safe for women over 40 who do not smoke.
- Take them each day. Twenty-five percent of women miss or skip days. Failure to take pills every day can result in pregnancy.
- When you are prescribed a new medicine, tell the healthcare provider that you are on the pill. Some medicines, such as penicillin, some sleeping pills, tuberculosis medicines and anxiety medicines will keep birth control pills from working.

Breast Feeding

Medicines taken when women breast feed may be passed to their children. Those women taking medicines and breast feeding should talk with their physician. Physicians will weigh the risks and benefits of their patient's particular medicine and their medical condition.

Do not stop any prescribed medicine without talking to your doctor!

North Carolina Medical Society, PO Box 27167, Raleigh, NC 27611

Hormone Therapy

Estrogen can help a woman during and after menopause or after a hysterectomy. This drug has many benefits and some risks. For example:

- It can relieve vaginal dryness and "hot flashes." It may also reduce some health risks. These include osteoporosis, which makes the bones brittle, and heart disease.
- It may increase the risk of breast cancer. It can also cause menstruation to resume. There may be long term effects we don't yet know.

Talk with your doctor to determine your risks and to decide if this therapy is right for you.

Common Problems in Women

About half of all women take their medicines improperly. When a course of treatment isn't followed, the medicine may not work. The most common problems:

- Taking less than prescribed
- Stopping too soon
- Taking more than prescribed
- Failing to refill prescriptions

What Can You Do?

- Get involved in the decision-making about your treatment. When you're involved, you'll feel better about following the prescribed treatment.
- Don't be afraid to talk with your doctor. If problems arise from the medication, or from the prescribed schedule, changes may be possible.

Common Problems in Older Women

Older women (and men) often take several medicines at the same time. Older people frequently have chronic diseases such as arthritis, high blood pressure, heart disease, lung disease and diabetes. Long-term treatment of one or more of these may mean a woman takes five or six medicines at once. This can lead to three major problems:

- Medicines may block or over-enhance the effectiveness of one another;
- Medicines may cause adverse reactions;
- Multiple medicine use makes it difficult to keep track of all the times and days that the medicines should be taken.

What Can You Do?

- Ask your doctor to schedule a time to review all of your medicines. Bring all your prescription and non-prescription medicines (people often use a brown bag). The health

care professional will check them for safety and review your medication schedule to help you take them properly.

- Tell each of your doctors about any medicines other doctors have prescribed. This will help them avoid prescribing medicines that shouldn't be mixed.
- If possible, use a pharmacy that keeps computer records of all the medicines you take. A system like this can help spot problems when a new prescription is filled.

Children and Medicine

Medicines can help your children feel better and stay active. Sometimes they even save lives. To work the way they should, though, they must be used properly. When we make mistakes in the way we give medicines, children don't get well. Some mistakes cause problems that can put your child's health—and life—at risk. The common mistakes that hurt children's health include:

- Stopping a medicine too soon or too suddenly
- Not giving enough of a medicine (forgetting or skipping doses or giving them at the wrong times)
- Letting a child refuse to take a medicine (or deciding on your own not to follow the doctor's advice)
- Giving too much of a medicine (giving larger doses or giving them more often than advised)

How can you be sure that you do what's best for your child? The first step is to speak up. Talk to your doctor, your children and those who take care of your children about every medicine they take.

Talk to Your Doctor

- Discuss the decision to begin or continue use of any medicine. Find out about other approaches that may be used along with medicines.
- Ask your doctor to explain the benefits and the potential risks of medicines he or she prescribes for your child.
- Tell your doctor about other medicines your child is taking, including over-the-counter medicines. This can help prevent drug interactions.
- Never stop, or adjust, the dosage of your child's medicine without consulting the doctor.
- Monitor and report on your child's response to the medicine. If you think it is causing side effects, let the doctor know. Don't be afraid of "bothering" him or her. Doctors

need feedback to give the best care.

- Call your doctor or pharmacist if you have other questions later on. Don't "guess" when it comes to medicines.

Talk to Your Child

- Teach your children that proper use of medicines is a key to good health, just like eating right and brushing their teeth.
- Explain the difference between legitimate medicines and illegal drugs. Use the term "drugs" to refer to illegal substances.
- Encourage your children to ask questions of healthcare providers.
- Decide together which responsibilities you and your child will have in following the treatment. A younger child might help you remember each dose; a teenager might take the lead, with you monitoring and providing back up.
- Get your child's help in solving problems that make it hard to follow treatment, such as remembering medicine in a busy schedule, taking medicines in school and coping with side effects.

Talk to The Others

Who Care For Your Children

The Other Parent—

Both parents and step-parents should be involved in helping the child take medicine. Share information you get from the doctor. Explain instructions. Clarify the roles each of you will play.

Grandparents, Day Care Helpers, Baby-sitters—

Explain the medicine schedule and treatment details to all those who give your child medicine in your absence. Follow up to be sure your instructions were carried out.

Schools and Teachers—

Tell school personnel if your child is taking a long-term medicine or if a dose is needed during school. Involve the teacher or school nurse in watching for side effects, problems in taking medicines, or other problems.

Medicine and Older People

While people of all ages sometimes use more than one medicine, older people use more medicines in combination than any other age group. They are also disproportionately affected by the problems that can result: adverse medicine interactions, avoidable side effects, overdosing, taking unneeded medicines and decreased compliance with the proper

medicine regimen. Some facts:

- Older people often visit more than one physician, each of whom may prescribe one or more medicines. Without good communication, each physician may be unaware of the patient's other prescriptions.
- Older people are more likely than other age groups to be taking four or more medicines at the same time. Older women in one study took an average of 5.7 prescription drugs and 3.2 over-the-counter medicines at the same time.
- The frequency of adverse reactions increases as the number of prescribed drugs increases. In one study, nearly 30% of older patients taking more than six medicines were hospitalized because of adverse drug reactions, compared with 10.8% taking only one medicine.
- Multiple medicine use increases the likelihood of noncompliance, because different dosing schedules can be confusing, easy to forget and inconvenient.

As an older person, what can you do to avoid medication problems?

- Talk to your physician about the information you need. You are not bothering them by asking questions. Also tell them about other medicines you are already taking.
- Write down questions in advance and possibly send them to the physician before a visit to signal the need to allow time for discussion.
- Don't suddenly stop taking medications. With some medicines this can be very dangerous.
- Tell your physician about over-the-counter medicines (e.g., laxatives and aspirin), drinking beer or wine and smoking. These can interfere with the medicines you are taking.
- Ask your physician about memory aids such as timers, clever medicine packaging and medicine calendars to assist you in taking your medicine.

General Tips For Using Your Medicines Safely

When an individual or family uses medicines correctly, they can cure illness and prolong or improve the quality of life. When used improperly many adverse effects can occur. Through the use of some simple rules problems can be avoided and the medicines can do their job.

Do

- Call your physician immediately if you experience unpleasant or unusual reactions to a medicine.
- Keep medicines away from children—out of sight and out of reach.
- Store medicines properly. Always read the label for special storage instructions.
- Consult your physician regularly to see whether there are any medicines you can cut back on or stop taking altogether.
- Post phone numbers in your home of your physician, emergency medical service, hospital and pharmacy.

Don't

- Discontinue your medication or change dosage without consulting your physician, even if you're feeling better.
- Use someone else's medication or give yours to another person.
- Keep medicines that have lost their labels, medicines that have passed their expiration dates or those that look changed or decayed.
- Transfer medicines to other containers, unless OK'd by your physician or pharmacist.

- Take medicines in the dark. Turn on the lights to avoid taking the wrong medicine.
- Take medicines unless you understand all the instructions for using them safely.

Prescription Labels

Be sure you understand all instructions on the medicine label and follow them exactly. Make sure the label includes your name, directions for using the medicine and the medicine's expiration date. Be sure you can read the label—have your pharmacist use large type, if necessary. Pay attention to any warning stickers on the container. If you have questions about your prescription, just ask your physician or pharmacist. □

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1992

November, December *Prescription Drug Use*

REMEMBER
1975?

JANUARY 1 H.R. HALDEMANN, JOHN C. MITCHELL AND JOHN D. EHRLICHMAN, FORMER TOP AIDES OF PRESIDENT RICHARD NIXON, ARE CONVICTED OF CONSPIRACY TO OBSTRUCT JUSTICE IN THE WATERGATE CASE. **FEBRUARY 11** MARGARET THATCHER IS ELECTED LEADER OF THE CONSERVATIVE PARTY, BECOMING THE FIRST WOMAN TO HEAD A BRITISH POLITICAL PARTY. **APRIL 30** THE SOUTH VIETNAMESE GOVERNMENT SURRENDERS TO THE COMMUNISTS, ENDING THE WAR IN VIETNAM. ♦ **SEPTEMBER 29** THE MALPRACTICE SITUATION IN NORTH CAROLINA REACHES A CRISIS AFTER THE LAST COMMERCIAL INSURANCE COMPANY ANNOUNCES IT WILL NO LONGER PROVIDE MALPRACTICE COVERAGE IN THE STATE. ♦ **OCTOBER 1** IN MANILA, MUHAMMED ALI DEFEATS JOE FRAZIER IN THE FIFTEENTH ROUND TO RETAIN THE WORLD HEAVY-WEIGHT BOXING TITLE. ♦ **OCTOBER 23** NORTH CAROLINA PHYSICIANS CREATE A MUTUAL INSURANCE COMPANY TO ASSURE A STABLE, FAIR PROFESSIONAL LIABILITY MARKET. ♦ THE YEAR'S TOP FILMS INCLUDE *JAWS*, *ONE FLEW OVER THE CUCKOO'S NEST*, AND *NASHVILLE*.

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Politics and Medicine

The *Journal* Interviews the Candidates For Governor of North Carolina

Edward C. Halperin, M.D., Deputy Editor

Editor's Note: In 1988 the *North Carolina Medical Journal* published interviews on health policy with Lieutenant Governor Robert Jordan, Democratic candidate for Governor, and incumbent Governor James Martin, Republican candidate for re-election. The interviews met with favorable response, so we decided to repeat the process in 1992. We are pleased to present, on the following pages, interviews with James Gardner, Lieutenant Governor of North Carolina and Republican candidate for Governor, and James Hunt, former Governor of North Carolina (1977-1985), and current Democratic candidate for the office.

Earlier this year I contacted the press officers for the Gardner and Hunt campaigns and requested interviews on health policy issues for the *North Carolina Medical Journal*. I supplied both candidates with copies of the 1988 interviews with Jordan and Martin. Approximately one month before the scheduled interviews, I submitted a list of topics for discussion: tobacco, rural hospitals, abortion, and animal research. Health policy issues are quite complicated and I did not want "snap" answers or "sound bites." Rather, I wanted to give the candidates and their staffs adequate time to prepare for the interviews and, if necessary, to research the subjects.

I was scheduled to interview former Governor Hunt at his Raleigh law office. As usual, I got lost going the wrong way on the Raleigh Beltline but successfully made it there

with about 10 minutes to spare. After working my way through two receptionists and one staff assistant I was able to spend one hour with former Governor Hunt.

I interviewed Lieutenant Governor Gardner at his official office in the old state house building in downtown Raleigh. I spent a congenial half hour with the Lieutenant Governor. Lieutenant Governor Gardner was not completely prepared to discuss the questions at the time of our interview. He pleaded the time demands of presiding over the State Senate. A few weeks later he submitted written clarifications of some of the material we discussed during the interview. They are included in the text.

In both cases, I recorded the interviews on my office dictaphone (so much for sophisticated audio-visual equipment!). Almost nobody speaks in complete sentences, not even candidates for Governor. Therefore, I have taken the liberty of editing the material to make it more understandable.

The *Journal* is pleased to serve as a forum for open debate on public policy and health issues, matters of special importance to medical practitioners. We hope that the following interviews will interest and inform our readers and prompt them to go to the polls in November and vote for the candidate of their choice. The interviews are presented in alphabetical order: Lieutenant Governor Gardner first, followed by former Governor Hunt.

Lieutenant Governor Gardner

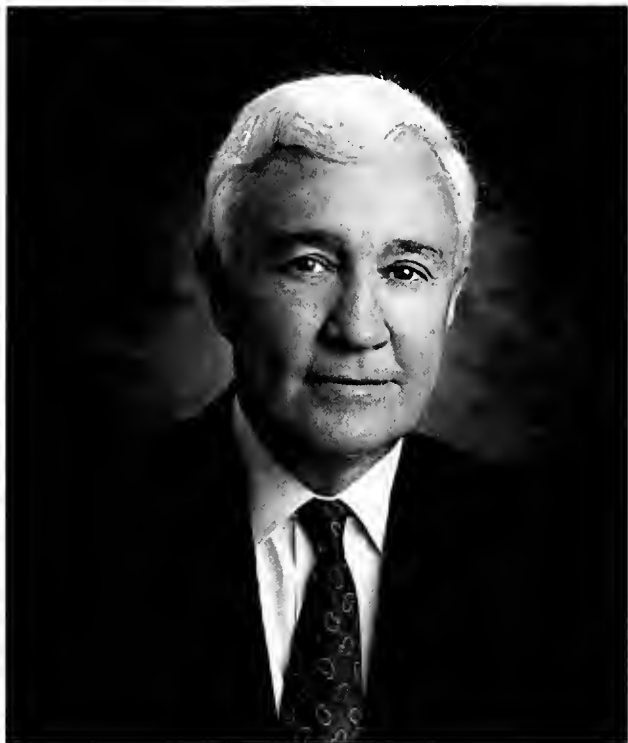
Halperin: Lieutenant Governor Gardner, both you and former Governor Hunt have received written copies of my proposed questions. I would like to begin with the first question.

Gardner: I would rather answer these questions in writing and have an opportunity to look at them and be sure that we

totally understand the questions and their political ramifications—particularly concerning the legislature. I want to go back and research the questions and see what bills may have some tie-in.

Halperin: Perhaps we can, in general, talk about the questions and leave you the option of providing written material later. Did you find any of the questions confusing? Are there any

From the Department of Radiation Oncology, Box 3085, Duke University Medical Center, Durham 27710.



James Gardner, Republican candidate for Governor

points that you would like clarified? For example, concerning the issue of tobacco. Some would suggest that there is an inherent contradiction in the office of Governor of North Carolina. On one hand, you are sworn to promote the economic well-being of the state and tobacco is a crucial part of the state's economy. On the other hand, it is well-recognized that tobacco is the leading preventable cause of death and disability in the adult population. Thus, the Governor is faced with promoting tobacco, and simultaneously attempting to discourage its use. Is there an inherent contradiction? How do you deal with it?

Gardner: Well, I think I would really rather give you written answers to give us an opportunity to double check them. A very good friend of mine who is now in the Senate is a doctor and I would like to sit down with him and have his input. I try to find people who are really more familiar with the issues. If you want to talk about the restaurant business now I can talk about that all day long. But when you get into some of these other [issues...].

I think the questions were pretty straightforward. But there are just a couple of things—for example, on infant mortality we are currently conducting a statewide \$350,000, in-depth survey of the effect of drugs and alcohol on unborn children. We have some preliminary results back, and I want to incorporate them in my answer. We have worked very

closely with Duke in fact. We have some statistics that I think tie into that, and I wanted to be sure to have them included.

But basically, what we have said on tobacco is that it is a legal substance in North Carolina. We think that the government is doing a very good job educating non-smokers and smokers on its potential health hazards. The number of people who are smoking today versus 10 to 15 years ago is smaller. Outside of education I want to say that the government should not be getting into restricting various businesses in what they can do. I think it is an education job, and I think [government is] doing a pretty good job in the public areas.

Halperin: Recently, the American Medical Association joined with the Surgeon General of the United States in attempting to force the R.J. Reynolds Company to restrict the "Joe Camel" advertising program. The argument is that Joe Camel is more recognized by children than, for example, Mickey Mouse. Some would say that, in fact, the Joe Camel advertising program is specifically aimed at inducing children to smoke. Do you think it would be appropriate to restrict certain forms of tobacco advertising?

Gardner: I was astounded at the Joe Camel [controversy]. I spent all of my life in business and in marketing and advertising. I am not a smoker myself, I don't pay much attention to smoking, and I was astounded at an article I read that gave the number of people, particularly the young people, [who] could identify Joe Camel. That really surprised me. Particularly with the restrictions that are already in television, you don't see smoking advertised much.

Halperin: But some surveys of children have suggested that Joe Camel is very highly recognized by children—in fact more than Mickey Mouse.

Gardner: I would question that survey. I believe that if you asked every child, most of them would know who Mickey Mouse is, but I don't believe they would know who Joe Camel is. You can do anything you want with surveys. I think the government has done, particularly in the area of tobacco, a very effective job in education. My grandchildren, for example, are very well versed in "cigarette smoking is bad for you." My daughter doesn't smoke, unfortunately my son-in-law does, and all of the education is kind of overturned when they see him smoking at home. He wants to quit and he is very aware of his parental responsibility. Now he goes outside to smoke, when he used to smoke right in the house.

It astounds me to see the success [of education]: If you had asked me 20 years ago if could we turn around tobacco use by educating people, I would have said no, but it's been done. This gives me hope that we can do likewise for drugs and other things.

Halperin: So your view on restricting tobacco advertising is?

Gardner: No. Because I think they have already gone almost beyond what I have been comfortable with. I get very nervous when the government starts getting involved in free enterprise and telling people what's right and what's wrong. I think tobacco companies have a responsibility to tell people if something can be harmful to them, and they have done a very good job. To stop somebody from advertising a product bothers me. I don't have a great deal of faith in government.

[Written answer submitted later]: Tobacco is a legal substance. The government is doing a good job of educating citizens about the hazards. And the tobacco companies are following governmental guidelines concerning packaging warnings. Our emphasis should be on warning users about potential hazards—not restricting trade of North Carolina's largest legal cash crop.

Halperin: Let's discuss a recurring political issue in the state's health policy—rural hospitals. Many rural hospitals are threatened with closure because of decreased bed occupancy, the pull on patients of secondary and tertiary referral centers in our larger cities, and unfavorable reimbursement. Some have said that the state ought to have a role in somehow “propping up” rural hospitals. Yet some people say that the free market ought to have its way and rural hospitals that are not economically viable ought to be allowed to close. What is your view?

Gardner: I know the federal government is already doing a great deal in that area. Speaking from the state's standpoint, we are already propping up more than we could profit. How much can we keep assuming on a state level and how many times can we raise taxes? The average person in North Carolina is having a hard time making ends meet, and we just had the largest single tax increase in the history of this state.

An awful lot of the state and most of the federal programs are entitlement programs, and we just simply can't carry that load. I think we should start looking very carefully at commitments we are making and this happens to be one area. If we have existing federal programs I am in favor of taking advantage of them, but I am not in favor of the state biting off any more than it can handle. Particularly when we have situations like those that exist in eastern North Carolina. We have a fine medical school and hospital facility in Greenville. In the past, if you were 30 to 40 miles away from there you'd have to go a long way to get to Chapel Hill or Duke. Now with East Carolina we have a fine regional hospital serving rural North Carolina. So I would be very leery of the state taking on any more responsibilities propping anything else up. They are having a hard time meeting the commitments they have right now.

[Written material submitted later]: One problem is a lack of health insurance. We need to ensure citizens have

health insurance by working to contain costs and by providing tax credits for insurance.

Rural hospitals can help themselves by forming partnerships with large hospitals to provide a wider array of services. They can also determine what specific health care needs their community requires and target their services to meet those needs.

We need to take full advantage of federal programs designed to help rural hospitals stay open. We have already qualified as one of seven states that will participate in the Essential Access Community Hospital Program.

Halperin: Another issue that comes up over and over is abortion. I talked at some length with former Governor Hunt on this issue. If the Supreme Court overturns *Roe v. Wade*, the state will have to face several difficult issues. The readers of the *North Carolina Medical Journal* would appreciate your views on several specific issues concerning abortion such as laws concerning parental consent for a minor's abortion, the size of the state's abortion fund, and whether or not, as Governor, you would support restrictions of abortions performed at the state-supported medical schools in Chapel Hill and Greenville.

Gardner: Mr. Hunt and I differ on this issue. He is in favor of the women's right for an abortion with no limitations. I am opposed to abortion except in cases of documented rape or incest or life-threatening situations to the mother. I am strongly in favor of parental consent. I am not sure what Mr. Hunt's position is on that but that's probably one of the major issues in which we differ.

[Written answer subsequently submitted by Mr. Gardner]: I would continue to uphold the law [*Roe v. Wade*] until such time as the Supreme Court overturned it.

Halperin: I'd like to discuss animal research, which forms an important part of laboratory investigation at the state's research universities and at pharmaceutical companies and other biomedical research companies. With the growth of the so-called “animal liberation” movement, and the number of laboratory break-ins, physical threats, and violent acts directed against animal research, the North Carolina Legislature passed, last year, a law to “render criminal the act of interference with animal research.” If you are elected, how strongly will you enforce this law? What are your views on state policy concerning the research use of animals?

Gardner: Well, this is an issue that I have some pretty strong feelings on. I support [these laws]. When somebody breaks the law and breaks into a facility like that they need to be prosecuted vigorously. If they want to change things, they need to change the law through the political process.

I happen to think that we need this type of research. I am an animal lover. I have had a dog almost all of my life,

and I hope that we use humane approaches to dealing with these animals. But the bottom line is that we have to have this research for human beings, and I think that has been proven beyond any shadow of doubt.

I am very concerned about the overzealousness of people not only in the animal rights area but in the area of abortions. I recently watched on television a mother who was pro-abortion and disliked the Supreme Court ruling. She said she would totally disregard the law and would go out and start protesting. We are a nation of laws, and if we want a change, we are going to have to do it through the process. Everybody might not like the process but it has worked for more than 200 years. We need to perfect it and make it work better and not go marching down the street and doing things of that type.

So I would strongly support the law even though I consider myself an animal rights activist because I care for animals and understand the role that they play.

[Written material submitted later]: I am confident that the professionals who conduct animal research treat the animals as humanely as possible. We must remember that work with animals is vital to medical research. There is no substitute for live animal specimens in research.

As for the protesters, we must not limit their rights to free speech. But when they trespass, or otherwise break the law, they should be prosecuted to the fullest extent of the law. We cannot afford to let a few radicals stand in the way of research that may benefit our whole society.

Halperin: I would like to talk about some general philosophic issues. I recently attended a conference in Washington, D.C. One of the speakers, a political scientist, argued that there really is no fundamental difference between the Democratic and Republican parties when it comes to health policy. He suggested that health policy, being a very complicated issue, was not carefully followed by the public. So, when faced with a complicated issue in health policy, politicians call in the "best and brightest" for their views. Then a consensus is reached. Thus, the political scientist argued, whether a Democrat or Republican is in office, we still come up with a general consensus view on health policy. Do you think there is a difference between the Democratic Party and Republican party philosophies on health policy?

Gardner: I think that it depends almost entirely on the issue. If you are talking about abortion I think there is a very clear-cut difference in the two parties, the two candidates, and probably the next Governor of our state. The role of government in many areas is absolutely different according to the philosophy of the two parties. The Republican party has always (and certainly in my case) felt that we need to limit the role of government as much as we possibly can. Mr. Hunt and the Democrats favor a much larger, more active, more involved government.

The health care [area] probably gets fuzzy because what we have hasn't worked out. I think both parties, and candidates on the national level, are very frustrated and are looking for answers. You are right in saying that we bring in the specialist and say, "Here is the problem, now give us some guidelines and recommendations on what area we should move in our state." In particular, the Governor is operating from a very weak position. He doesn't have a veto and consequently he can't tell the General Assembly, "Here's my basic philosophy." In most cases they don't pay very much attention, and it doesn't make any difference [whether the Governor is] Democrat or Republican.

Until we have a veto and the Governor can put some teeth in what he does, the General Assembly pretty well marches to its own drum. We are the only state where the governor doesn't have a veto, and once you get into that hodgepodge of people [in the legislature] and ideas, it is democracy at work [and it's] pretty much of a stalemate. You don't get general consensus on an issue as complicated as health care. When you deal with legislators who come from rural areas, you have a perspective from that particular area. You have them coming from the big cities; 21 of the 50 members of the Senate are lawyers so they bring a different perspective into it. It is a complicated issue.

Halperin: Recently some members of the North Carolina State Legislature have introduced bills to consider using North Carolina as a "laboratory" for innovative health care reform. They cite, for example, the attempts to try new forms of health care access/insurance in Massachusetts or Oregon. Do you feel that, as Governor, you would push for new innovations in health care policy for the state, attempting to use it as a "investigational social laboratory" for the rest of the country?

Gardner: I would probably say no. North Carolina is not the place to do it because you have a weak governor here. If you had a governor with a veto, a line item veto like in 43 other states, then he [would have] a hammer that he could hold over the General Assembly and say, "Let's sit down and talk and solve this issue." At least then we [could] be bold enough to move in a new direction and let North Carolina be a model. The Governor would have clout to back that up. Right now he doesn't have it. Whether it is Jim Gardner or Jim Hunt they [the legislature] pretty well does what it wants to do and...consequently I have not felt, in the four years that I have been here, that we have had very effective legislative leadership. It gets back to the fact that we are the only state where the governor doesn't have veto. We have that system of checks and balances, but it is imbalanced here. It is too heavily legislative right now, and that greatly effects things that we are talking about. If anybody says, "Oh yes we ought to be a model state, and as Governor I would go over there and do it," they are not going to be able to deliver. □

Former Governor Hunt

Halperin: Mr. Hunt, it seems to me that a candidate for Governor of North Carolina is asking for a job with an inherent contradiction. On one hand, the Governor needs to attend to the economic well-being of the state and its citizens. This includes the promotion of agricultural products that are major contributors to the state's economic well-being. Unquestionably, tobacco heads the list. On the other hand, the Governor is required to pursue a policy that supports the health of the population. There is no question that tobacco-related illness is the major preventable form of disease in the United States. Each of us pays, in tax dollars and increased insurance premiums, for the tobacco habit. How do you reconcile the inherent contradiction of tobacco for a North Carolina politician?

Hunt: Tobacco is important to our economy in North Carolina. So is the health of our people. We will continue to grow tobacco in this state. It is a primary source of income for many of our families. We also have an obligation to our people to educate them about the hazards of tobacco and certainly about excessive smoking. We must particularly see that young people and expectant mothers are warned of these hazards. We should educate everybody, but those are two groups that I am keenly aware of that need to have special education and warnings. The Governor of North Carolina should ensure that the state and its agencies provide that kind of education.

Halperin: What is your opinion concerning proposals to further restrict tobacco advertising? There have been suggestions, for example, that tobacco advertising potentially aimed at children, such as the "Joe Camel" campaign, or at minority groups ought to be restricted. What is your view?

Hunt: I am not going to try to restrict advertising. That's not good government. I am saying that you ought to educate people about the dangers, particularly the two groups I mentioned. And that means when you are putting out information you do it honestly and forthrightly.

Halperin: What is your view concerning having taxes represent the true societal cost of tobacco? Some have suggested that the tax on tobacco ought to be raised considerably so that the resultant revenue could pay for the costs that tobacco imposes on all of us.

Hunt: I am opposed to raising taxes on tobacco. I don't think that is the way to go about it. If you start trying to calculate the societal cost of everything, including the sugar that we put in food that we ought not to, too much salt, and all the rest, I don't think you can do it—it's too complicated.



James Hunt, Democratic candidate for Governor

Halperin: Let's discuss the abortion issue. With the recent Supreme Court decision in the Pennsylvania case, I believe that we can expect additional pressure on the states to clarify their abortion laws. A particularly complicated issue is that of parental consent for a minor's abortion. Some individuals feel that required parental consent for a minor's abortion will foster family communication. Others feel that family communication is not influenced by laws requiring parental consent for a minor's abortion. They also feel that such laws ignore the possible physical and emotional abuse that a teenager might be subjected to by a biological parent when the issue of an abortion is raised. What is your view on this?

Hunt: I think that parents ought to be involved in this decision concerning their children. And I think that pregnant girls ought to be encouraged to discuss abortion with their families. There are too many cases of child abuse and incest in families for us to require that discussion by law. Girls who feel that they have the right kind of relationship with their families will discuss it with their parents. They should. They need support systems. The family should be the best resource. But it should not be required by law.

Halperin: During the administration of Governor Jim Martin, and with the acquiescence of the State Legislature, the state abortion fund has decreased substantially. This has affected the ability of indigent women to obtain a state-funded abortion. In your opinion, should the state abortion fund remain at its reduced level, be restricted further, or be enlarged?

Hunt: I favored an adequate state abortion fund during my terms as Governor. We did have a state law providing for this. We should have such a fund and there should be adequate funds to provide this service to people who are too poor to pay for it.

Halperin: Some people have suggested that the Governor of North Carolina ought use his/her influence to restrict abortions conducted at the state-supported medical schools in Chapel Hill and Greenville. What is your view on this?

Hunt: That's wrong. There should be no such restrictions.

Halperin: Let's turn to a discussion of rural hospitals.

Hunt: Don't you want my view on *Roe v. Wade*?

Halperin: The readers of the *North Carolina Medical Journal* are particularly interested in your views on specific topics concerning abortion. I don't think we need to have a philosophical discussion on the general issue of *Roe v. Wade*.

Hunt: You mean to tell me that doctors in this state aren't interested in whether North Carolina is going to change its law as to whether it is legal or not to have an abortion?

Halperin: I think your views on *Roe v. Wade* can be inferred. It would be logically inconsistent for you to support further restrictions on abortion and have the views that you have already stated. If you wish, however, I will be happy to have you state your views on *Roe v. Wade*.

Hunt: I oppose any efforts to change North Carolina laws that give a woman the right to choose.

Halperin: Fine. Shall we talk about rural hospitals?

Hunt: I'm a fellow who lives in the country and grew up in the country. Let's talk about rural hospitals.

Halperin: We read, frequently, of rural hospitals that have closed or are threatened with economic extinction based on reduced bed occupancy and restricted reimbursement. Some people say that the state ought to have a role in financially supporting these rural hospitals. Other people feel, however, that the free market should have its way and that the state

should not intervene if rural hospitals are not economically viable. What do you think?

Hunt: I think that every North Carolinian deserves access to quality and affordable health care including rural care. I believe that we must have strategies to help many of the rural hospitals stay open. I understand that about one-fourth of them are threatened. I think there are a number of things that we can do. One is to try to link them up with other hospitals—larger hospitals. I know that some [linking] is done. I think we need to work harder at doing that. There is a federal program called the Essential Access Community Hospital Program that has been particularly successful with this. I think we ought to look at the state in terms of regions and try to encourage larger hospitals in the cities—Asheville for example—to give all the help that they possible can to the rural hospitals and clinics. I think that is part of it, to link rural hospitals to larger hospitals and have different kinds of facilities [so] that doctors can go back and forth and do some of their practice and deal with some of their patients [in both].

I think that part of the answer is to help the small hospitals. Maybe a hospital needs to add a nursing home as a part of it. I think we have to be creative about it.

I think we have to work extra hard to see that we have primary care physicians in rural areas. We ought to consider something like a state health corps—sort of like the National Health Service Corps or whatever it is called. Some of our doctors out there today were in that corps. Maybe the state needs to do something like that. When I was Lieutenant Governor we established, and I was a big part of establishing, the East Carolina University medical school. I put the funds for the facility in my first budget as Governor. That medical school has as one of its primary purposes training and educating primary care physicians with the hope that those people will go into areas that need primary care service, particularly rural areas in our state.

I think we need to look at all of our medical schools and see if we are doing as many things as we can to encourage people to practice in rural areas, including the selection of students. I know that things can change, but I think that if a student comes from a rural area that needs doctors badly and intends, by however we determine, to go back there and practice, or if that person maybe didn't have the greatest grades in the world, or maybe that person is a minority, or they may not be quite the top students that are seeking admission, but there are other things that say, "Hey, if this student makes it, it is quite reasonable that they will be successful, we believe that the chances of them going into practice in a rural area is much better than some other students," then I think those ought to be matters we give real weight to in the selection process.

I think all of these are things that we can do, and I think that we ought to look at [them] very hard. I recently heard on

National Public Radio that there is actually a bias against practicing in rural areas in terms of reimbursement for certain kinds of health services. Somebody in Washington made a decision that it costs less to practice a certain kind of medicine and perform certain kinds of procedures in rural areas and are paying lower fees for it. It has turned out in fact that is not the case—at least the difference is not nearly as great.

There is an actual bias working against rural health. I think that the Governor needs to lead our state in finding ways to keep enough hospitals open around the state so that people can get health care without having to go too far. Exactly how far is too far will obviously vary. It may depend on what kinds of roads you have. But we have to have accessible health care, and if that means we need some kinds of supplements at times, then maybe that is something we have to do. I do not believe that you say “the heck with the people.” You know that if there isn’t enough money coming in here under the present set-up to provide health care for these people then they will have to go without it. I think that is wrong.

Halperin: Racial minorities are among the groups potentially underserved by medical practitioners. Are you talking about offering specific preference for admission to state medical schools to minority students?

Hunt: I am not talking about just minority students. I am talking about rural students, inner-city students.

Halperin: But isn’t the notion of an “inner-city student” another way of saying a minority student? Aren’t socioeconomically disadvantaged medical students more likely to be minorities? With all the discussion in Washington about race-based scholarship, I think we need to clarify this point.

Hunt: Let me make my point very clear. I am talking about giving extra weight to students who come from and are highly likely to return to underserved areas. It is not a race-based argument. It is an underserved argument.

Halperin: But the underserved are often minority or socioeconomically disadvantaged populations.

Hunt: They are. Look at the areas that need doctors, and if you have got some good students who are very qualified and who can confidently pass their courses and become good doctors, and you believe that the chance is very good that they are going to go back into that rural area and practice, give them some extra weight.

Halperin: Are you suggesting admissions preference to state medical schools to individuals from rural areas who are more likely to return to practice in those areas? This seems, to me,

analogous to encouraging a “public service requirement.”

Hunt: That’s what we are getting at there, and I don’t know exactly what is available out there. We have some of those available but I suspect that it is very little.

Halperin: But isn’t a significant part of the problem the crushing amount of student loans? When medical students are faced with repaying \$40,000 to \$80,000 in student loans, that can considerably influence their choice of a specialty and practice location. Could one way of encouraging students to practice in rural areas include reduction in loans if they practice for a period of time in a rural area?

Hunt: That’s also how you get them into rural parts of North Carolina. And they have settled in those areas, because if they came there they got to like the people, they enjoyed the people, they found some things that they originally hadn’t appreciated about the area until they got there and then decided to stay there.

Halperin: Some members of the North Carolina State Legislature have suggested that North Carolina ought to consider innovative, and to some extent, experimental programs in health care delivery. The argument offered is that, if the federal government will not move quickly on health care reform, then states can, in essence, serve as “laboratories” for new innovations in health care reform and health care delivery. What is your view?

Hunt: I have been hoping that the federal government would come up with a national approach to this—and I don’t have my own plan—but they haven’t done anything. I mean they haven’t passed the Walker plan or the George Bush plan or anybody else’s plan. I think we want to wait and see now, after the 1992 elections, whether or not the national government puts a national approach to this in place that turns out to be helpful in terms of better care and reasonable cost. If they don’t, then we have no choice. We have to come up with an approach of our own to do the best we can.

Halperin: For example?

Hunt: Education, in particular early childhood education, is critical. Nothing comes ahead of education. We are going to have to do lots of balancing in our approach. The states will have to spend time and effort on health care if the federal government doesn’t. I think it is increasingly likely that we are not going to have any big comprehensive approach, but the states are probably going to have to supplement whatever kind of approach the federal government finally comes up with. So we are going to have to be creative, we are going to have to work together, and I think that the government ought to do this.

If I am elected Governor I will call a summit of health care providers and employers, insurance companies, and others, and through a very well-considered process come up with a plan that will make sense for our state. I am reading a lot of these state plans. I know something about Oregon. I know something about what Minnesota has just done and some of these others, but I don't have a specific plan to lay in front of you today for North Carolina. But I will see it as my job to lead us in dealing with this issue if that becomes necessary. You have to have people involved who know most about it and who care deeply about this. I would expect North Carolina physicians to be very deeply involved, particularly those people who are involved in good primary care. I want us to put our primary emphasis on how we prevent bad things from happening. How do we prevent children from being born with terrible medical problems that are very costly and hurtful to them and limit their lives?

My whole approach to things will be: "How do we spend our money and exert our efforts in such a way that we have less illness and fewer babies who are born with considerable problems or who develop them in early life?"

Halperin: Many people feel that your biggest "return on the dollar" in health care is in preventive medicine for the very young.

Hunt: I want us to put special emphasis on teaching children skills they'll need in order to be good parents. It is very important that in school our children get educated in areas [the family planning kinds of areas in general]. I think they need to understand that when you become a parent these are the things you have to be aware of and these are the things you should do to be a parent—to have a healthy baby.

I think that expectant mothers need to have very good prenatal care. They need to have very good nutrition. They need to learn how to take care of babies. They obviously need to be under a doctor's care and have their babies delivered by doctors [or by] trained midwives or something of that sort—good care—the best that they can get. Then we have to see that infants in early years get the kind of medical care and nutrition that they need and then the kind of help to have their brains grow and their self images develop.

Halperin: North Carolina has a large biomedical research community both in its universities and in private industry. This research community often relies on experimental animal research for scientific investigation. In recent years the so-called "animal liberation" movement has threatened and directed acts of violence against animal research facilities. North Carolina, via the State Legislature last year, passed a law making it a crime to disrupt an animal research laboratory. Do you support or oppose this law? If elected Governor, how strongly would you enforce it?

Hunt: I would enforce that law as vigorously as it possibly could be. Animal research is absolutely essential for the health and well-being of our citizens. There are regulations about how animals are to be used, but if I become Governor of this state, people who threaten or use violence toward this kind of research will be vigorously prosecuted. The laws will be very strongly enforced.

Halperin: I would like you to consider a bit of a philosophical question. Recently I attended a conference in Washington, D.C., at which a political scientist made the argument that the Democratic or Republican parties don't have philosophies on health care. This political scientist argued that, following election to public office, politicians always call in the "best and brightest" in health care to provide solutions and suggestions. The public, mystified by the complexities and intricacies of health care, cannot focus on these complex issues. Thus, whether you are a Democrat or a Republican, you pursue a consensus policy in health care without any overriding philosophy pushing you one direction or another. Do you accept this proposition?

Hunt: I think there is a Democratic Party philosophy. We put our greatest value on people to help them become all they can be. That obviously means that they have to have good health care and good nutrition. Again, children's little brains are developing and they have to grow. Children have to be stimulated, nourished, and nurtured, and they have to have what it takes to be their best. But you can have people in either party who feel strongly, are activists, that will use public policy.

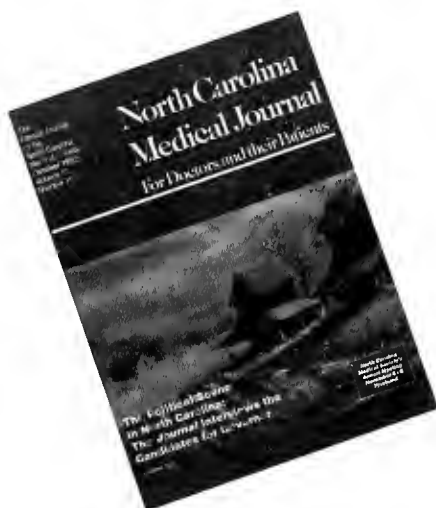
I think one has to use the party as a guide, but the views of the candidate and their records as effective leaders are very important. For example, what can a Governor get done in terms of working across the state with the medical community and with hospitals, encouraging them to work with rural hospitals? What can a Governor get done and what can medical schools do when we say, "Hey, now we expect you to really focus, you are getting state money? We expect you to really focus on trying to recruit prospective doctors for underserved areas." We might even make it a part of the law.

A Governor needs to be able to be successful in working with the state legislature to get bills through to provide funds for things like the abortion fund for poor women. Obviously the Governor's own personal views are important. So the party philosophy has something to do with it, but the individuals who are running it are also important. □

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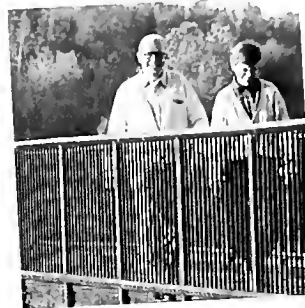
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Outcome at One Year in Infants with Chronic Lung Disease Receiving Comprehensive Follow-Up Care

A Regional Experience in North Carolina, 1984-1990

T. Michael D. O'Shea, M.D., M.P.H., Robert G. Dillard, M.D.,
Deborah C. Gillis, RN, BSN, Barbara Jackson, RN, BSN, and Kurt L. Klinepeter, M.D.

Introduction

Bronchopulmonary dysplasia, also called neonatal chronic lung disease, is a major cause of morbidity in premature infants.¹ This disorder occurs almost exclusively in pre-term infants who are treated with assisted ventilation. Characteristic findings, which usually resolve during the first one to two years of life, include a variable degree of respiratory insufficiency and airway obstruction, both of which worsen during upper respiratory infections.²

The etiology of neonatal chronic lung disease is poorly understood. There is some evidence that it is caused, at least in part, by traumatic injury to the neonate's lung during assisted ventilation and by toxic effects of high concentrations of oxygen used to treat pre-term infants with acute respiratory illnesses.^{2,4} Recent epidemiologic studies indicate that when the infants are female^{3,4} or when the mother has had antenatal treatment with glucocorticoids⁵ there is a decreased risk that chronic lung disease will develop; when the infants are of white race or younger gestational age, there is increased risk.^{3,5}

Estimates of the prevalence of this

disorder range from 22% to 26% of surviving very low birth weight neonates (those with birth weight less than 1,501 grams, who are nearly always premature).^{1,6} Since survival rates for very premature infants improved during the 1980s, it is likely that the number of infants with neonatal chronic lung disease also increased. In North Carolina each year, about 1,600 very low birth weight infants are born and about 1,200 survive; thus we estimate that nearly 300 infants develop chronic lung disease each year in North Carolina.

Most longitudinal follow-up studies of infants with chronic lung disease have emphasized their high rates of mortality and morbidity as compared to very low birth weight infants without chronic lung disease. Several studies have indicated that 4% to 13% of infants with chronic lung disease die after discharge from the hospital and that 15% to 29% of survivors have major developmental problems.⁷⁻¹⁰ One limitation of prior studies of outcome in chronic lung disease is that these studies used hospital-based, as opposed to geographically based, samples. In addition, most studies describe infants born

in the late 1970s and early 1980s rather than those born (and treated) more recently. In this paper we describe the outcomes at one year of 194 very low birth weight infants (birth weight less than 1,501 grams, or 3 pounds 5 ounces), who developed chronic lung disease, and who were born between July 1, 1984, and June 30, 1990, to mothers residing in a single perinatal care region in northwest North Carolina.

Over the six-year period studied, the prevalence of chronic lung disease among surviving very low birth weight infants was stable. However, among infants with chronic lung disease, the rate of death after discharge from the hospital and the prevalence of major developmental problems decreased markedly. This improvement in outcome among infants with chronic lung disease was coincident with our development, starting in 1986, of a comprehensive follow-up program for such infants. Because of its possible role in improving the outcome of infants with chronic lung disease, we describe this program in some detail.

To allow an assessment of the role of our program in improving outcome, data

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Commentary

by Ernest N. Kraybill, M.D.,
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Progress in medicine is often a matter of taking a few steps forward, then slipping a step backward. This is especially true of neonatal medicine. The forward leap in survival rates associated with the aggressive treatment of respiratory distress syndrome in premature infants two decades ago was followed by a disturbing slide backward—the emergency of a new disease, bronchopulmonary dysplasia, often called "chronic lung disease." This complication results in prolonged hospitalization and is associated with impaired growth, increased respiratory morbidity in the early years, and impaired neurodevelopment. The economic impact of this disorder is so great that some authorities claim that it is not cost-beneficial to provide intensive care to neonates with birth weights less than 1,000 grams¹ and even less than 1,500 grams.²

O'Shea and colleagues describe a significant step forward in the journey toward improved outcome of premature infants. With a comprehensive outpatient follow-up program, they have shown that very low birth weight infants with chronic lung disease can be discharged safely to their parents, earlier than would be possible otherwise. Surely, this results in financial savings, although cost is not reported in their article. Moreover, their program observed a remarkably low post-discharge mortality rate and a developmental impairment rate only slightly higher than that of similar birth weight infants who did not have chronic lung disease.

The program described by O'Shea et al is a model, not only for premature infants with chronic lung disease, but also for other chronic illnesses that are increasingly prevalent in childhood. Efforts to develop and fund such programs deserve the same priority that was attached to the development of neonatal intensive care units two decades ago.

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- 2 Boyle MH, Torrence GW, Sinclair JC, et al. Economic evaluation of neonatal intensive care of very low birth weight infants. *N Eng J Med* 1983;308:1330-1337.

are presented for three groups: a group born before the program was implemented, a group born during the early development of the program, and a group born after development was complete and a mature program was in place. Although analyses of the type presented here, in which historic controls are used, may not provide conclusive evidence of an intervention's benefit, they do give encouragement for future studies using concurrent controls.

Comprehensive Follow-Up Care for Infants with Chronic Lung Disease

Most infants with chronic lung disease require prolonged treatment with supplemental oxygen and multiple medications, sometimes for as long as a year after birth.² Because of their complex medical needs, infants with chronic lung disease may be hospitalized for as long as a year after birth. Alternatively, infants may be discharged home still using oxygen and medications, if the family is prepared to meet the complex needs of their infant. Because of a serious shortage of chronic care hospitals for children, only a small proportion of infants with chronic lung disease reside in such facilities.

The ability to use supplemental oxygen at home decreases length of hospitalization as well as medical care costs for infants with chronic lung disease.¹¹⁻¹² On the other hand, home care of oxygen-dependent infants is not free of problems.¹³⁻¹⁴ Families caring for an oxygen-dependent infant may become socially isolated as a result of difficulty in taking the infant outside of the home and the unavailability of respite care providers. Typically, one or more family members must give up working outside of the home during the period of supplemental oxygen dependency. This may mean, for single parents, that the family is no longer covered by health insurance.

Medical services for infants with chronic lung disease tend to be fragmented and consist of frequent visits to

multiple providers, often with inadequate communication between providers. Private physicians may be unable to provide the frequent detailed evaluations needed by infants with chronic lung disease and may be unprepared to treat these infants because of limited experience with this disorder.

In 1986, we developed, with assistance from the Kate B. Reynolds Health Care Trust, a comprehensive follow-up program to address some of the problems of infants with chronic lung disease. The goals of the program are:

1. To shorten the period of hospitalization for infants with chronic respiratory disorders, thereby lowering health care costs, and,
2. To provide comprehensive post-discharge medical, nursing, and social services, so that earlier discharge does not increase the risk of morbidity or mortality.

The program's staff includes a neonatologist, a nurse, a social worker, and a secretary. Participation begins before an infant is discharged from neonatal intensive care. The program's nurse and social worker attend weekly discharge planning rounds in the Intensive Care Nurseries at Brenner Children's Hospital and Forsyth Memorial Hospital. At these rounds, infants eligible for the program are identified and hospital and program staffs establish communication links.

In all cases in which oxygen use at home is planned, the program's social worker visits the infant's home before discharge. During such visits, the home environment, support system, and family coping abilities are assessed, and plans for the infant's care are reviewed. After discharge, the program's nurse makes a home visit. The nurse's assessment includes pulse oximetry at rest and during a feeding, and the nurse reviews plans for the infant's care, including a schedule of clinic visits, with the family.

Case Management

Case management is an important program component. Most infants require

the services of multiple professionals, including developmental pediatricians, physical therapists, audiologists, and pediatric ophthalmologists. Case management helps avoid duplication of services and facilitates compliance with scheduled appointments. Equally important is the consistent source of emotional support that case management provides for the family. Many infants require the services of home health agencies. In such cases the program's staff helps to identify the optimal provider for needed services.

During clinic visits, the social worker assesses the parents' coping abilities, their psychological status, and their social supports. Based on this assessment she decides what supportive interventions are needed and helps the family gain access to these resources. The nurse then carries out a physical assessment and pulse oximetry, and laboratory tests are performed as required by the infant's medical condition. The physician reviews the medical history and physical examination, and the social worker, nurse, and physician discuss their findings and develop a plan for management. This plan is discussed with the family and is written out for the primary care provider and com-

munity agencies serving the infant (e.g., early intervention programs). The program strives to complement rather than duplicate the care administered by an infant's primary care providers.

In all cases supplemental oxygen is provided by nasal canula. A flow rate is used that maintains arterial oxygen saturation consistently above 92% and results in a rate of weight gain that is normal, based on an infant's age adjusted for prematurity. Typical oxygen flow rates are 0.1 liters to 1.0 liters per minute. At each clinic visit we consider whether the oxygen can be weaned. If the rate of weight gain has been satisfactory (based on comparison with standard growth curves) and if, after decreasing the flow of oxygen by 0.1 liter/minute, the oxygen saturation is consistently above 92%, then the flow rate of oxygen is decreased by 0.1 liter/minute. A small minority of infants are treated with bronchodilators (albuterol or metaproteronol), and a slightly larger group are treated with diuretics, but the majority of infants are treated with neither.

The frequency of clinic visits depends on the severity of an infant's illness, although infants using supplemental

oxygen are seen in clinic at least once a month. All infants are screened with the Denver Developmental Screening Test-II at four months of adjusted age (postnatal age minus weeks of prematurity). At one year of adjusted age infants are examined using the Bayley Scales of Infant Development.¹⁵ Also at that time a pediatrician performs physical and neurological examinations.

Outcome at One Year for Infants with Chronic Lung Disease

In ascertaining the sample of infants with chronic lung disease whose outcome we describe, we defined chronic lung disease as present in all infants who were using supplemental oxygen at 36 weeks post-conceptual age. Shennan et al found this definition to be better correlated with future respiratory illness than the more common definition (use of oxygen at 28 days of chronological age).¹⁶

Our geographically based sample of infants with chronic lung disease represents all cases of chronic lung disease identified among a cohort of very low

Table 1. Neonatal characteristics, survival, and prevalence of chronic lung disease of very low birth weight neonates

	Pre-Pgm*	Early-Pgm*	Late-Pgm*
Number of neonates	289	313	385
Birth weight	1,042 (570-1,450)	1,068 (547-1,470)	1,070 (571-1,446)
Gestational age	28 (23-33)	28.5 (24-33)	29 (23-34)
Male	136 (48%)	169 (54%)	215 (56%)
White race	183 (63%)	202 (65%)	227 (59%)
Assisted ventilation	207 (72%)	223 (71%)	273 (71%)
Survived to discharge	220 (75%)	238 (76%)	288 (75%)
Chronic lung disease	54 (25%)	65 (27%)	75 (26%)

*Key: Pre-Pgm = period before development of the Program (1984-86);

Early-Pgm = first two years of Program (1986-88);

Late-Pgm = last two years of Program (1988-90).

Assisted ventilation represents number of neonates requiring assisted ventilation treatment; chronic lung disease represents number of neonates needing supplemental oxygen at 36 weeks post-conceptual age. Data are presented as numbers (%) of infants, but birth weight (in grams) and gestational age (in weeks) are given as medians (with 5th and 95th percentiles in parentheses)

Table 2. Baseline attributes of infants with chronic lung disease

	Pre-Pgm*	Early-Pgm*	Late-Pgm*
Number of infants	54	65	75
Birth weight	905 (637-1,350)	900 (628-1,400)	977 (645-1,446)†
Gestational age	28 (24-31)	28 (24-32)	28 (25-32)
Male	34 (63%)	38 (58%)	47 (63%)
White race	37 (69%)	43 (66%)	48 (64%)
Outborn	8 (15%)	14 (22%)	13 (17%)
Small-for-gestational-age	26 (48%)	23 (35%)	28 (37%)
Mother married	39 (72%)	41 (63%)	44 (59%)
Mother's schooling	12 (10-16)	12 (9-16)	12 (10-16)
Mother's age	25 (18-35)	24 (18-37)	26 (18-35)

*Key: Pre-Pgm = period before development of the Program (1984-86);

Early-Pgm = first two years of Program (1986-88);

Late-Pgm = last two years of Program (1988-90).

Data are presented as numbers (%) of infants, but birth weight (in grams), gestational age (in weeks), mother's education (in years of schooling), and mother's age (in years) are given as medians (with 5th and 95th percentiles in parentheses).

†Median birth weight was higher in late-Pgm period ($p = 0.03$, Wilcoxon rank sum test)

Table 3. Neonatal illnesses in infants with chronic lung disease

	Pre-Pgm*	Early-Pgm*	Late-Pgm*
Number of infants	54	65	75
Pneumothorax	16 (30%)	12 (19%)	18 (24%)
Pulmonary interstitial emphysema	19 (35%)	13 (20%)	15 (20%)
Patent ductus arteriosus surgery	28 (52%)†	6 (9%)	15 (20%)
Cranial ultrasound findings normal	20 (37%)	35 (54%)	43 (57%)
Uncomplicated SEH/IVH	17 (32%)	21 (32%)	25 (33%)
IPE/complicated IVH	17 (32%)‡	9 (14%)	7 (9%)

*Key: Pre-Pgm = period before development of the Program (1984-86);

Early-Pgm = first two years of Program (1986-88);

Late-Pgm = last two years of Program (1988-90).

Data are presented as numbers (%) of infants. Abbreviations for ultrasound findings: SEH/IVH = uncomplicated subependymal or intraventricular hemorrhage; IPE = intraparenchymal echodensity.

†The percent of infants treated with surgery for patent ductus arteriosus was higher in the pre-Pgm group ($p < 0.001$).

‡The percent of infants with IPE or complicated intraventricular hemorrhage was higher among pre-Pgm infants ($p < 0.003$)

Table 4. Duration of hospitalization and use of supplemental oxygen in infants with chronic lung disease

	Pre-Pgm*	Early-Pgm*	Late-Pgm*
Number of infants	54	65	75
Days of hospitalization†	112 (49-246)	105 (62-168)	89 (48-163)
Number given home oxygen‡	20 (37%)	34 (52%)	50 (66%)
Days on oxygen§	95 (47-235)	113 (47-461)	148 (53-477)

*Key: Pre-Pgm = period before development of the Program (1984-86);
 Early-Pgm = first two years of Program (1986-88);
 Late-Pgm = last two years of Program (1988-90).
 Data show median number of days (with 5th and 95th percentiles in parentheses) or number (%) of infants using home oxygen.
 †Decrease in days of hospitalization is significant ($p < 0.001$ by Cox Proportional Hazards regression, controlling for birth weight, gestational age, surgery for patent ductus arteriosus, and occurrence of pulmonary interstitial emphysema).
 ‡Increased use of home oxygen is statistically significant, $p = 0.001$, chi square for linear trend.
 §Difference in days on supplemental oxygen is not statistically significant ($p = 0.18$, logrank test)

program was complete, the post-hospitalization mortality rate decreased more than five-fold (Table 5). In fact, our most recent data show no deaths among the infants with chronic lung disease born in 1990 and 1991 and followed in the program. During the six-year period of our study, there was a progressive decrease in the percentage of infants with cerebral palsy or delayed mental development (Table 5).

Table 6 compares the risk of various unfavorable outcomes among infants with chronic lung disease, relative to very low birth weight infants

birth weight (500-1,500 grams) neonates having the following characteristics: (1) born July 1, 1984, to June 30, 1990, to a mother residing in a 17-county region of northwest North Carolina; (2) admitted to one of two intensive care nurseries (at Brenner Children's Hospital and Forsyth Memorial Hospital); and (3) having no major developmental anomaly. The six-year period over which these neonates were born includes two years before the initiation of our comprehensive follow-up Program (pre-Pgm infants), the first two years of Program development (early-Pgm infants), and the subsequent two years in which the Program was regarded as well-developed (late-Pgm infants). Over this six-year period the survival rate for very low birth weight infants (75% to 76%) and the prevalence of chronic lung disease among surviving infants (25% to 27%) were stable, as shown in Table 1.

Characteristics of the 194 infants who developed chronic lung disease are summarized in Table 2. Among these infants there was a slight increase over time in the average birth weight, but little change in terms of gestational age, the proportions for gender and race, and the socioeconomic status of the mothers, as indexed by years of education, age, and

marital status (Table 2).

As shown in Table 3, complications of prematurity were highly prevalent. Overall, 24% of the infants had pneumothorax, 25% required surgery for patent ductus arteriosus, and 49% had intracranial bleeding. The prevalences of pulmonary interstitial emphysema, surgery for patent ductus arteriosus, and severe intracranial abnormality (intraparenchymal echodensity or complicated intraventricular hemorrhage) were significantly higher in the two pre-Program years, as compared to the four Program years. The second and third two-year periods were similar in terms of complications of prematurity.

As Table 4 shows, there was a progressive decline in the average duration of hospitalization, coincident with an increase in the proportion of infants discharged home on oxygen following development of our program. On average, infants born in the late-Program period spent 23 fewer days in the hospital than those born in the pre-Program period.

We might expect infants discharged at younger ages and lower weights to be more vulnerable to medical problems. Despite this expectation, in the late-Program period, after the development of our

without chronic lung disease. The effect of chronic lung disease on outcome is expressed as the odds ratio. (Odds are calculated as the proportion of a group that has a given characteristic divided by the proportion of the group that does not have the characteristic. For example, if 75% of a population has brown eyes, the odds that any member has brown eyes is .75/.25 or 3:1). The odds ratio is calculated by dividing the odds for a given characteristic (such as an outcome of death as shown in Table 6) in one population (for example, premature infants with chronic lung disease) by the odds for the same characteristic in a second population (for example, premature infants without chronic lung disease). In Table 6, an odds ratio of one indicates that chronic lung disease has no effect on the risk of the outcome in question, whereas an odds ratio of two indicates that chronic lung disease puts infants at twice the risk for that outcome. Over the six-year study period, odds ratios decreased for most outcomes, indicating that the risk of unfavorable outcomes among infants with chronic lung disease became more similar to the risk of those outcomes among those without chronic lung disease.

Table 5. Outcomes at one year of age (adjusted for prematurity)

	Pre-Pgm*	Early-Pgm*	Late-Pgm*
Number of infants	54	65	75
Died†	4 (7.4%)	6 (9.2%)	1 (1.3%)
Followed to one year of age	51 (94%)	64 (98%)	74 (99%)
Rehospitalization			
none	22 (41%)	29 (44%)	36 (48%)
one	20 (37%)	17 (26%)	23 (31%)
two or more	12 (22%)	19 (30%)	16 (21%)
Weight less than 5th percentile‡	41 (75%)	29 (44%)	36 (48%)
Head less than 5th percentile	17 (32%)	21 (32%)	19 (25%)
Cerebral palsy	12 (23%)	11 (17%)	9 (12%)
Mental development index <68◊	16 (30%)	10 (16%)	10 (13%)
Psychomotor development index <68¶	21 (38%)	18 (28%)	14 (19%)

*Key: Pre-Pgm = period before development of the Program (1984-86);

Early-Pgm = first two years of Program (1986-88);

Late-Pgm = last two years of Program (1988-90).

†Comparison of post-discharge mortality for early-Pgm and late-Pgm infants gives $p = 0.05$.

Comparison of pre-Pgm and late-Pgm infants gives $p = 0.16$ by Fisher's exact test.

‡A higher proportion of pre-Pgm infants had weight less than the 5th percentile of normal ($p = 0.05$, chi square test).

◊A higher proportion of pre-Pgm infants had Mental Developmental Index <68 ($p = 0.05$, chi square test).

¶Chi square test for linear trend gives $p = 0.03$ for decrease in proportion of infants with Psychomotor Developmental Index <68

Table 6. Ratio of odds that very low birth weight infants with chronic lung disease will have abnormal outcomes at one year, relative to very low birth weight infants without chronic lung disease

	Pre-Pgm*	Early-Pgm*	Late-Pgm*	*Key: Pre-Pgm = period before development of the Program (1984-86); Early-Pgm = first two years of Program (1986-88); Late-Pgm = last two years of Program (1988-90). Values in parentheses show 95% confidence limits for odds ratio.
Number of infants	54	65	75	
Death	6.6 (1.1, 51.9)	2.8 (0.7, 10.7)	1.4 (0, 18.9)	
Cerebral palsy	2.4 (0.9, 5.9)	1.5 (0.6, 3.5)	1.5 (0.6, 3.5)	
Mental development index <68	5.9 (2.2, 16.6)	2.4 (0.9, 6.6)	1.6 (0.6, 3.9)	
Psychomotor development index <68	6.6 (1.7, 8.7)	2.8 (1.5, 7.8)	1.4 (1.0, 4.9)	
Weight less than 5th percentile	9.5 (4.2, 22.0)	1.8 (1.0, 3.9)	2.2 (1.2, 4.1)	
Rehospitalization	1.7 (0.8, 3.4)	2.1 (1.0, 4.1)	2.5 (1.4, 4.5)	

Discussion

We have described the findings from longitudinal follow-up of a large, geographically based cohort of infants with chronic lung disease born in the last half of the 1980s. The major conclusion we can draw from these findings is that the outcome of infants with chronic lung disease has improved since the mid 1980s. Further, chronic lung disease has only a modest effect on the health and development of very low birth weight infants who receive comprehensive follow-up care. Unless an infant has some other risk factor for developmental problems (e.g., intracranial hemorrhage), parents can be counseled that the risk of major developmental problems (cerebral palsy or low mental or psychomotor developmental indices) is only slightly higher than the risk among very low birth infants who do not have chronic lung disease.

We can only speculate as to the reasons for the improvement in outcome that we have observed. We do think that the comprehensive multidisciplinary follow-

up program developed at our institution during the six-year period of our study has had a beneficial effect on infants with chronic lung disease. We observed a marked increase in the number of infants discharged home on supplemental oxygen and an accompanying decrease in the duration of hospitalization of infants with chronic lung disease. Since length of hospitalization of very low birth weight infants is a strong predictor of developmental status during infancy,¹⁷ our follow-up program may have improved the developmental achievement of infants with chronic lung disease by shortening the period of neonatal hospitalization. In addition, some of the improvement in developmental outcome may reflect our practice of early referral to developmental intervention programs.

An issue not addressed by our study is whether infants with chronic lung disease, who are free of major developmental problems at one year of age, will manifest developmental problems such as learning disabilities in later life. To study this issue, we are presently carrying

out assessments at age five years of the infants whose status at one year we describe in this report.

The most serious limitation of our study is its use of historical controls. As with any new and expensive intervention, the effects of our program should be rigorously measured before widespread application is advocated. We are seeking funding for a study of the effect for comprehensive follow-up, in which appropriate controls would be used.

Notwithstanding the uncertainty about the reasons for the improvement in outcome among infants with chronic lung disease, the information presented here should be useful for neonatologists and families and professionals serving infants with chronic lung disease. If comprehensive follow-up care is provided, and other risk factors (such as intracranial hemorrhage) are absent, infants with chronic lung disease are at only modestly increased risk of major developmental problems relative to other very low birth weight infants and at very low risk of post-hospitalization mortality. □

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Continuing Medical Education

October 5-9

MRI Minifellowship

Place: Winston-Salem
Credit: 32 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 5-9

Adult Echocardiography

Place: Winston-Salem
Credit: 25 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 7-9

North Carolina

Environmental Health Law

Place: Raleigh
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

October 7-11

1992 Duke Urologic Assembly

Place: Pinchurst
Credit: 12.5 hours Category I, AMA
Info: Office of CME, DUMC, Durham 27710. 919/684-6485

October 10-11

ACLS Course

Place: Chapel Hill
Credit: 15.5 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 800/862-6264

October 13

Better Collection

Practices for Your Office

Place: Greensboro
Info: W. Alan Skipper, Executive

Assistant, Conferences, 222 N. Person St., North Carolina Medical Society, Raleigh 27611. 919/833-3836

October 13-15

7th Annual On-Site

Sewage Conference

Place: Raleigh
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

October 14

Better Collection

Practices for Your Office

Place: Research Triangle Park
Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, 222 N. Person St., Raleigh 27611. 919/833-3836

October 15

Better Collection

Practices for Your Office

Place: Wilmington
Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, 222 N. Person St., Raleigh 27611. 919/833-3836

October 15

Biannual Cardiology

Update and Review

Place: Asheville
Credit: 5 hours Category I, AMA
Info: Barry Fox, Assoc. Dir. of Continuing Medical Education, 501 Biltmore Ave., Asheville 28801. 704/257-4400

October 16

Ovarian Cancer: Present And Future Directions In Clinical Management

Place: Research Triangle Park
Credit: 6 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

October 20

Better Collection

Practices for Your Office

Place: Asheville
Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, 222 N. Person St., Raleigh 27611. 919/833-3836

October 21

4th Annual North Carolina

Conference on Injury Control

Place: Chapel Hill
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

October 22-24

Recent Developments

In Internal Medicine

Place: Atlantic Beach
Credit: 15.5 hours Category I, AMA
Info: Mary C. Valand, Office of Continuing Medical Education, Box 7224, Greenville 27835-7224. 919/551-5208

October 22-24

Duke Fall Symposium in OB/GYN

Place: Asheville
Credit: 13.5 hours Category I, AMA
Info: Office of CME, DUMC, Durham 27710. 919/684-6485

October 22-25

5th National Conference

On Professional Well-Being

Place: San Francisco, CA
Fee: Varies

Info: Marjorie Harrison, Ph.D., Society for Professional Well-Being, 21 W. Colony Place, Suite 150, Durham, NC 27705. 919/419-0011

October 23-34

Frank R. Lock OB/GYN Symposium

Place: Winston-Salem

Credit: 7.5 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 23-24

BGSM Alumni Weekend

Place: Winston-Salem

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 23-25

13th Annual Mountain

Medical Meeting

Place: Asheville

Credit: 12 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 26-30

Neurovascular Ultrasound

Place: Winston-Salem

Credit: 25 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

October 28-29

Strengthening Supervisory Skills for Health and Human Service Professionals

Place: Winston-Salem

Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

October 29-31

Assisted Technologies

Annual Meeting

Place: Charlotte

Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/961-2118

November 2-6

Peripheral Vascular Ultrasound

Place: Winston-Salem

Credit: 25 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 4-6

3rd Annual Physician

Office Lab Symposium

Place: Winston-Salem

Credit: 18 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 4-8

North Carolina Medical Society Annual Meeting

Place: Pinehurst

Info: W. Alan Skipper, Executive Assistant, Conferences, North Carolina Medical Society, 222 N. Person St., Raleigh 27611. 919/833-3836

November 5-8

North Carolina Dermatology Association

Place: Pinehurst

Info: H. Mendall Jordan, M.D., 919/781-1001

November 7

North Carolina Society of Pathologists

Place: Pinehurst

Info: John D. Shellburne, M.D., 919/286-6925

November 7

Fluoroquinolones in the 1990s

Place: Research Triangle Park

Info: Office of CME, DUMC, Durham 27710. 919/684-6485

November 7

North Carolina Urological Association

Place: Pinehurst

Info: Floyd Fried, M.D., 919/966-2571

November 6-7

North Carolina Society of

Plastic and Reconstructive Surgery

Place: Pinehurst

Info: William A. Lambeth, III, M.D., 919/872-2616

November 9-10

Mammography Minifellowship

Place: Winston-Salem

Credit: 16 hours Category I, AMA

Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 12

American College of Surgeons

NC Chapter Annual

Cancer Symposium

Place: Charlotte

Credit: 5 hours Category I, AMA

Info: Joel Vickers, Dr. P.H., Dir. Continuing Medical Education, P.O. Box 32861, Charlotte 28232-2861. 704/355-3942

November 12-13

Advanced Cardiac Life

Support (ACLS) Provider Course

Place: Raleigh

Credit: 16 hours, AAFP

Fee: \$150

Info: Helen Creech, R.N., Course Coordinator, Rex Hospital, 4420 Lake Boone Trail, Raleigh 27607. 919/783-3161

November 13

3rd Annual Public Health

Social Work Seminar Series

Place: Winston-Salem

Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

November 13

What's New with Health Services Information

Systems in North Carolina (Teleclass)

Place: Chapel Hill, Greenville, Greensboro, Winston-Salem, Charlotte, and Asheville
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

November 13-14

Arts Medicine Seminar

Place: Winston-Salem
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 16-20

Obstetrical Ultrasound

Place: Winston-Salem
Credit: 25 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

November 18-19

Governor's Task Force Conference on Health Objectives for the Year 2000—Healthy Carolinians 2000

Place: Research Triangle Park
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

November 19-22

Duke Medical Alumni Weekend

Place: Durham
Info: Office of CME, DUMC, Durham 27710. 919/684-6485

November 20

Breast Cancer: Public Policy, Prevention, and Cost-Effectiveness

Place: Chapel Hill
Credit: 6.5 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

November 20-22

Winter Family Physicians Weekend

Place: Asheville
Info: Deborah W. Alford, NC Academy of Family Physicians, P.O. Box 18469, Raleigh 27619. 919/781-6467

December (date to be determined)

Overworked, Overwhelmed?

A Prescription for Healing (Teleclass)

Place: Chapel Hill, Greenville, Greensboro, Winston-Salem, Charlotte, and Asheville
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

December 1

Duke Tuesday in Urology

Place: Durham
Credit: 5 hours Category I, AMA
Info: Office of CME, DUMC, Durham 27710. 919/684-6485

December 4-5

7th Annual Sports Medicine Symposium for Primary Care Physicians

Place: Research Triangle Park
Credit: 11 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

December 4-5

Current Urologic Update

Place: Winston-Salem
Credit: 9 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

December 5

UNC Ophthalmology Residents Day

Place: Chapel Hill
Credit: 3.5 hours Category I, AMA
Info: Christine C. Cotton, UNC Department of Ophthalmology, CB #7040, 617 Burnett-Womack Bldg., Chapel Hill, 27599-7040 919/966-5296

December 5

4th Annual Lipid Symposium

Place: Research Triangle Park
Info: Office of CME, DUMC, Durham 27710. 919/684-6485

December 7-8

Mammography Minifellowship

Place: Winston-Salem
Credit: 16 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

December 9-11

1992 Health Promotion and Wellness Institute—Community Interventions in Tobacco Control: Strategies on the Cutting Edge

Place: Raleigh
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

December 9-11

Getting the Message Across for Environmental Health Specialists

Place: Kure Beach
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill, 27599-8165. 919/966-4032

December 11

Update on Mood Disorders

Place: Chapel Hill
Credit: 6.5 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

Continuing throughout the year Geriatric Education Modules

Place: Durham
Fee: \$10
Info: Geriatric Education Center, Box 3003, DUMC, Durham 27710. 919/684-5149

Cushing's Disease



This 21-year-old had hard-to-control hypertension and amenorrhea. Her mother, researching the topic in the encyclopedia, wondered about "a pituitary tumor." Her blood pressure was 140/100 on two medications; she had thin skin with multiple bruises, hirsutism, moon facies, pericervical (and truncal) fat excess including a "buffalo hump." Hemoglobin was 15 gm/dL and white cell count, 11,000. Testing showed excessive cortisol production; successful resection of a pituitary basophilic adenoma led to resolution of all abnormal findings.



Harvey Cushing: surgeon, author, artist, teacher—true scientist and Renaissance man. He combined clinical, laboratory, and epidemiologic skills in a lifelong study that created the foundation for much of pituitary endocrinology as we know it today. As Fulton, his friend and biographer, wrote shortly after his death in 1939, "In all he did, Cushing was a perfectionist...he had the temperament and the sensitive perception of an artist, but he also had the enduring patience of the scientist." His greatest satisfaction came from his roles as physician and diagnostician, which allowed him to recognize and describe the signs and symptoms of hypercorticism, the syndrome and the disease that bear his name to this day.

Cushing, the youngest of 10 children, was born April 8, 1869, in Cleveland, son and grandson of physicians. He attended Yale (where he played right field for the "baseball nine"), then Harvard Medical School. After interning at the Massachusetts General Hospital, he took surgical residency at Johns Hopkins under Halsted (1896-1900). He joined the surgical staff at Johns Hopkins concentrating in neurosurgery, especially the pituitary gland. His microscopic research in the Hunterian Lab led to one of his first scientific contributions: The pituitary gland was known to contain growth hormone producing cells that stained with eosin, but Cushing described "basophilic" cells in the anterior lobe that he postulated "probably elaborate some other essential secretion." Twenty years later he would link these basophilic cells to the clinical condition that bears his name; long after his death they would be shown to secrete ACTH.

In 1912 he returned to Boston where his early years on staff at the Peter Bent Brigham Hospital were spent perfecting the transsphenoidal approach to pituitary surgery. He also created a brain tumor registry which, by the time he retired, contained more than 2,000 cases that he had operated on. He was opposed, however, to narrow specialization, stating that "no one can be a good physician who has no idea of surgical operations, and a surgeon is nothing if ignorant of medicine." Furthermore, he was a proponent of the physical examination and believed that "students cannot begin to think in terms of the patient too early in their course, nor too early

begin to interpret and record what they can see, hear, and touch—perhaps even smell and taste—at the bedside."

This belief in clinical observation had led to his interest in a young Russian girl who had "painful adiposity" of the face, neck, and trunk, hypertrichosis, amenorrhea, and overdeveloped sexual characteristics. In 1912 he published *The Pituitary Body and Its Disorders* reporting her case with its classic description of the physical findings in hypercorticism (along with a detailed study of 46 other cases of endocrine disturbance). He recognized the hormonal basis of this "polyglandular syndrome," but he was uncertain "whether these symptoms were chiefly attributable to disordered pituitary, adrenal, pineal, or ovarian influences." He followed the patient for years, writing 22 years later that she was "in reasonably good health, though some of the stigmata of her malady still persist." He saw other patients with similar findings over the years; they rarely developed visual changes or increased intracranial pressure, they rarely resulted in operation. Death was seldom related to their disease, and autopsy reports usually described the pituitary as normal.

Cushing had suspected the existence of basophilic pituitary tumors, but only in 1924, after reading a paper by the Czech physician Raab describing a patient with a basophilic adenoma, did he realize their significance. Photos of Raab's patient "were so striking and bore such a close resemblance to the appearance of a patient...under observation in my own wards that I felt little doubt but that they had been afflicted in all certainty with the same disorder." He secured autopsy reports on all patients with this polyglandular syndrome and in 1931, his junior co-worker, H.M. Teel, discovered a basophilic tumor in such a patient. Cushing lectured on basophilic adenomas and the "baffling symptoms" of "polyglandular syndrome" to the N.Y. Neurological Society on January 5, 1932 (published as "The Basophil Adenomas of the Pituitary Body and their Clinical Manifestations" in the *Johns Hopkins Hospital Bulletin*). Since 1932, all patients with hypercorticism are said to have "Cushing's Syndrome," and those whose condition is caused by pituitary hypersecretion of ACTH have "Cushing's Disease." □

—Sharon C. Hathaway, M.D., Duke University Medical Center, Durham 27710

Adrenal Insufficiency After Removal of an Apparently Non-Functional Adrenal Mass

Cushing's Diathesis without Cushing's Syndrome

David DeAlkine, Jr., M.D.

Adrenal masses that had not been suspected or anticipated are discovered incidentally during 0.6% of abdominal computed tomography (CT) scans.¹ Such adrenal masses may represent benign and clinically inconsequential curiosities, but sometimes their serendipitous discovery can lead to life-saving treatments. The list of potential diagnoses includes adrenocortical adenomas, adrenocortical carcinomas, pheochromocytomas, lipomas, adenolipomas, cysts, ganglioneuromas, and metastatic tumors arising from other sites.² The risk to health from malignant masses is obvious, but even "benign" adrenal masses can pose a risk if they are hormonally active. In order to assess the functional status of incidentally discovered adrenal masses we usually screen by measuring the free cortisol and 17-ketosteroid excretion in a 24-hour urine sample (to detect Cushing's syndrome), and by measuring plasma or urine catecholamines (to detect occult pheochromocytoma). In this brief report, I describe a patient with an apparently non-functional adrenal mass and with no clinical signs of Cushing's syndrome who developed adrenal insufficiency and subsequently died after unilateral adrenalectomy. This sequence of events suggests that determination of plasma cortisols and even 24-hour urine free cortisol are not sufficient to detect all biochemically active adenomas.

The Patient

A 72-year-old woman was admitted for excision of right renal and adrenal masses. She had a long history of hypertension and type II diabetes. In 1972, she had developed Guillain-Barre syndrome and required mechanical ventilation and prolonged hospitalization. She recovered, but complained afterward of decreased strength in her back and lower extremities. She had suffered from depression for several years before admission.

By the family's report, the patient had become increasingly weak and withdrawn in the months prior to admission. Two

months earlier she had been admitted to another hospital for dehydration. During that admission an abdominal CT had revealed right renal and adrenal masses. Screening assessment of the adrenal mass had included a normal morning cortisol of 11 mcg/dL and a normal 24-hour vanillylmandelic acid (VMA) excretion.

After discharge, the patient lived with one of her children. On the day of admission she had fainted after using the restroom; she was admitted to another hospital. Medications at the time of admission included bupropion hydrochloride (Wellbutrin), nifedipine (Procardia XL), buspirone hydrochloride (BuSpar), and glyburide (DiaBeta). The patient, a widow, did not smoke or drink. She had no drug allergies. Family history was notable for lung cancer, but there was no history of endocrine neoplasms.

She was a thin (63 inches tall, weight 105 lbs.), elderly woman in no distress. Blood pressure was 140/80 without orthostatic change; pulse was 68. General physical examination was normal. Abdominal exam revealed no masses, obesity, or other abnormalities. She was alert but withdrawn, with symmetrical and normal strength, but decreased fine touch, pinprick, and vibratory senses below both knees. Skin showed no striae, bruising, or fragility.

Laboratory evaluation showed her hemoglobin to be 17.5 g/dL; leukocytes, 8,000 with normal differential count; sodium, 143 mmol/L; potassium, 4.3 mmol/L; chloride, 96 mmol/L; carbon dioxide content, 38 mmol/L; serum urea nitrogen, 12 mg/dL; creatinine, 1.3 mg/dL; glucose, 181 mg/dL. Baseline plasma cortisol was 11.6 mcg/dL, rising to 28.5 mcg/dL at 30 minutes and to 30.4 mcg/dL 60 minutes after ACTH injection. Abdominal CT scan demonstrated a mass in the right kidney whose appearance was worrisome for carcinoma and a 2 cm right adrenal mass. A 24-hour urine demonstrated a normal 24-hour urine cortisol excretion of 63.1 ug (normal 20-90) and had normal content of catecholamines (epinephrine < 10 pg/mL, norepinephrine 316 pg/mL, and dopamine < 10 pg/mL).

The patient was transferred to the Duke Surgical Service

From the UNC Medicine Teaching Service, Wake Medical Center, Raleigh.

for removal of the right renal and adrenal masses. Her immediately post-operative course was complicated by the development of hypertension followed by hypotension, hypoglycemia, fever, and worsening mental status. She was transferred to the medical intensive care unit and seen by an Endocrine consultant after an episode of hypoglycemia (fingerstick glucose of 11 mg/dL) and a systolic blood pressure of 80 mmHg. Plasma cortisol was 1.6 mcg/dL (normal >10) and rose to only 4.1 mcg/dL after ACTH (normal >20). Her 24-hour urine cortisol excretion was 7.9 mcg (normal for post-operative state not available; normal for the unstressed state = 20-100).

After replacement with intravenous dexamethasone sodium phosphate (Decadron) and then with intravenous cortisone sodium succinate (Solu-Cortef), the patient's hypotension and hypoglycemia resolved, but her mental status continued to decline (electroencephalogram suggested a metabolic encephalopathy) and her respiratory status worsened. The patient died after several days of respiratory failure.

Pathologic examination of the surgically excised adrenal mass revealed a 2.7 x 1.8 x 1.4 cm adenoma weighing 12.5 gms. No special staining procedures were performed. The excised kidney contained a benign multilocular cystic nephroma. On post mortem examination, the left adrenal gland was atrophic and weighed 4.4 gms.

Discussion

Although Cushing's disease frequently results in hyperglycemia and hypertension, and occasionally causes depression, these were chronic problems in our patient. Otherwise, she exhibited no physical stigmata of cortisol excess. Furthermore, she had normal pre-operative plasma cortisol levels, a normal 24-hour urinary cortisol excretion, and a normal ACTH stimulation test that was interpreted as showing an intact hypothalamic-pituitary-adrenal (HPA) axis. On the surface, it would seem reasonable to conclude that she had a non-functional adrenal mass.

Nevertheless, she developed post-operative hypotension and hypoglycemia, accompanied by very low 24-hour urinary cortisol values, and she had low basal and ACTH-stimulated plasma cortisol levels. At autopsy, there was atrophy of the remaining adrenal compatible with autonomous biochemical activity (cortisol secretion) of the excised adrenal mass leading to secondary atrophy of the contralateral gland. I can only conclude, then, that this patient's adrenal adenoma produced cortisol at a level sufficient to suppress the HPA axis and the contralateral adrenal, but not high enough to produce clinical Cushing's syndrome. Cortisol secreting adenomas are respon-

sive to ACTH, and this presumably accounts for the patient's "normal" pre-operative ACTH stimulation test. Although measurements of plasma cortisol and especially of 24-urine cortisol excretion are very good screening tests, they are *not* sufficient to rule out autonomous secretion of cortisol by an adrenal adenoma. For this purpose it is necessary to show that plasma or urinary cortisol fall normally in response to exogenous dexamethasone; the dexamethasone suppression test remains the "gold standard" for the diagnosis of Cushing's syndrome.

With more extensive use of abdominal computed tomography, ultrasound, and magnetic resonance imaging, physicians will increasingly encounter unsuspected adrenal masses. Copeland reviewed the diagnostic evaluation and management of incidentally discovered adrenal masses;² several points can be emphasized here. Primary adrenal cortical carcinomas are usually large at presentation.³ For this reason excision is recommended for adrenal masses larger than 6 cm in diameter or in cases where there is concern about adrenal metastases. Biochemical assessment should be carried out to detect those large tumors that have hormonal function (including functioning carcinomas).³ Adrenal masses that are less than 6 cm in diameter require biochemical assessment and those that are hormonally active (that is, with physical exam or laboratory evidence of Cushing's syndrome, female virilization, hyperaldosteronism, or pheochromocytoma) need excision.² Non-functional adenomas less than 6 cm in diameter need not always be removed, but do require periodic radiographic and hormonal re-evaluation to be sure that there has been no change in status.^{2,3}

In any event, it appears clear that thorough pre-operative biochemical assessment is crucially important, if only to prevent post-operative adrenal insufficiency. Recently, there have been reports of adrenal insufficiency occurring after removal of apparently non-functioning adrenal adenomas.^{1,4,5} Inoue et al⁴ report a patient with normal 24-hour urinary cortisol levels who did not suppress urinary cortisol excretion after dexamethasone administration. Imai et al⁵ report two patients with aldosterone-secreting adenomas and normal baseline cortisols whose serum cortisols did not suppress with dexamethasone.

I believe that these literature cases and our own recent experience suggest that, even in the absence of clinical stigmata of Cushing's syndrome, normal baseline plasma and urine cortisol levels are not sufficient to rule out a biochemically active adrenal adenoma. Copeland and others^{2,3} recommend that all patients with incidentally discovered adrenal masses undergo an overnight dexamethasone suppression test to detect autonomous cortisol secretion. Furthermore, patients with small adrenal masses that do not need excision should have interval biochemical testing to detect early evidence of cortisol producing adenomas. □

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Edited by Daniel Sexton, M.D.

Proverbs About Doctors

Do not dwell in a city whose governor is a physician.
—Hebrew proverb

All idiots, priests, Jews, actors, monks, barbers, and old women think they are physicians.
—Medieval Latin proverb

The more doctors the more diseases.
—Portuguese proverb

Fond of lawyer, little wealth; fond of doctor little health.
—Spanish proverb

Young doctors make humpy cemeteries.
—French proverb

A half doctor near is better than a whole one far away.
—German proverb

Until a physician has killed one or two he is not a physician.
—Indian proverb

A doctor's character should be square, his knowledge round, his gall bladder large, and his heart small.
—Chinese proverb

A doctor from a distance is like a blind eye.
—Hebrew proverb

Heaven fend me from a busy doctor.
—Welsh proverb

Happy is the physician who is called in at the end of the illness.
—Chinese proverb

A loquacious doctor is successful.
—Indian proverb

When the clever doctor fails, try one less clever.
—Bechuanaland proverb

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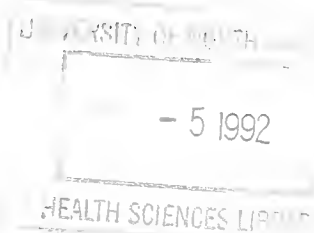
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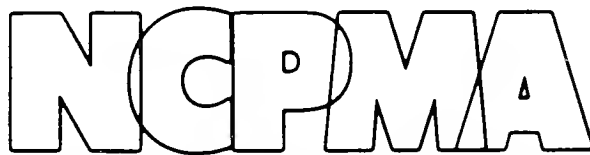
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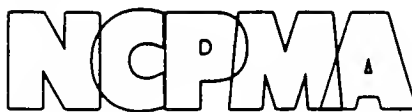


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Letters to the Editor



The Patient as Storyteller

To the Editor:

I was really moved as I read Dr. William Howell's article in the August issue, "The Content of One Doctor's Practice: Relevance of the Biopsychosocial Model" (NC Med J 1992;53:401-9). It seems to me to be a very thoughtful, succinct, and personal approach to some very difficult problems. I really liked the way Dr. Howell used some data to make points about somatizations and Balint agreements.

I think Dr. Howell's personal approach, with its database, is a very significant contribution to the literature. It encourages people to reflect on their own experience in a way that other articles cannot do. As I've experienced it, the pure storytelling personal approach often times seems apochryphal and not quite believable, even if absolutely truthful! More abstruse articles (say, on the three-function model or somatization) tend to be pretty dull unless one already knows that he or she has a definite interest in the material.

William D. Clark, M.D.
Medical Director
Addiction Resource Center
1356 Washington St.
Bath, ME 04530

Critical of Aphorisms

To the Editor:

The "Bulletin Board" item "Aphorisms of the Month: Lawyers and the Law" (NC Med J 1992;53:504) is offensive as a part of a professional journal "For doctors and their patients."

In the past, I have had the opportunity to request that our hospital newsletter not quote jokes or feature cartoons, which humorize the public's criticism of

our profession. My feelings concerning "Lawyers and the Law" is very similar.

Admittedly, these are substantial quotes, though out of context; nevertheless, this item does not belong in our journal.

Julian R. Taylor, M.D.
Ahoskie Family Physicians
Medical Arts Center
Ahoskie, NC 27910

From the Section Editor:

Since I am section editor of the Aphorisms of the Month, *Journal* staff forwarded your letter to me. I appreciate hearing from you about your opinions and will keep your comments in mind. Negative as well as positive feedback concerning this section is important to me.

Daniel J. Sexton, M.D.,
Associate Professor
Division of Infectious Diseases,
Box 3605, DUMC
Durham, NC 27710

Pneumonia Vaccine Reaction

To the Editor:

Have there been any reports of patients experiencing a reaction to pneumonia vaccine? I've had a female patient who had an adverse reaction to a shot of 0.5 of Pneumococcal Vaccine Polyvalent Pnu-Immune 23®. About five or six hours later she had tightness in her chest, a heavy flu-like feeling in her upper chest, congested cough, and general malaise. She reported that she stayed in bed for three days before she was able to get up. She did not call my office so no treatment was given.

Claude A. Frazier, M.D.
Doctor's Park - Bldg 4
Asheville, NC 28801

A Response for Dr. Frazier:

Pneumococcal Vaccine Polyvalent (Pnu-Immune 23® and others) is a vaccine consisting of capsular polysaccharide antigens from 23 of the most common varieties of *Streptococcus pneumoniae*.¹ The U.S. Public Health Service Immunization Practices Advisory Committee (ACIP) concluded that efficacy of the vaccine is well established in high-risk patient populations.^{2,3} Local reactions (such as erythema, soreness, swelling, and induration) occur in up to 90% of vaccine recipients within two to three days of administration and usually persist no more than 48 hours.^{1,4} Severe local reactions occur in less than 1% of patients.^{2,5} Low-grade fever (up to 40° C) has been reported in 3% to 7% of adult vaccine recipients.^{2,4} Weakness, myalgias, arthritis, headache, photophobia, chills, and nausea are infrequently reported.^{1,2} Rarely, rash, urticaria, serum sickness, arthralgias, adenitis, and asthenia have been observed.^{1,2} Despite administration of millions of doses of pneumococcal vaccine (including the previously available 14-valent preparation), only three poorly documented cases possibly related to vaccine product manufacturer have been reported.⁶ The manufacturer also cautions that hypersensitivity reactions may occur in patients with allergic reactions to components of the vaccine.^{1,2} Pnu-Immune 23® contains thimerosal 0.01% as an inactive ingredient.¹ Revaccination is recommended only in select populations, since adverse reactions (primarily local reactions) may increase with revaccination and may be correlated to circulating pneumococcal antibodies.⁷⁻⁹ Patients with past medical histories significant for pneumococcal infections may also have high levels of preexisting pneumococcal antibodies and may be at in-

creased risk of both local and systemic adverse reactions.^{1,4}

Chest tightness and cough following pneumococcal polyvalent vaccine have not been previously reported in the published medical literature. However, these symptoms may be consistent with a hypersensitivity reaction to the preparation. Reactions of general malaise are consistent with previous reports of such reactions. Based on the information provided in this case, we cannot definitely conclude that this patient had an immune-mediated complication of pneumococcal vaccine. Nonetheless, we advise against rechallenging this patient with further doses of pneumococcal vaccine.

Richard H. Drew, M.S., R.Ph.
Clinical Pharmacist, and
Daniel J. Sexton, M.D.
Associate Professor
Division of Infectious Diseases
Duke University Medical Center
Durham, NC 27710

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Mea Culpa

From the Editor:

Dr. W. Harding Kneeder of Davidson noted an error on page 531 of the October 1992 issue of the *Journal*. He is correct when he reminds us that the North Carolina state motto is *esse quam videri* (from the Latin "to be rather than to seem"). We had inadvertently printed the motto as *esse quam videre*. ("to be rather than to see"). Sorry we didn't see that.

Guidelines for Letters

All Letters to the Editor are subject to editing and abridgment. Letters should not exceed 500 words; longer submissions are welcome, however, and we will consider them for publication elsewhere in the *Journal*.

Letters must be typed, double-spaced, signed, dated, and include a phone number and address.

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Microsurgical Reversal Of Female Sterilization

A Community Hospital Experience

C.F. McDonell, Jr., M.D., FACOG, Pat Daughtrey, CST, Joyce Holloman, RN, and David Miller, RN

In 1986, Spivac¹ et al estimated that 10% of the six million American women who had been sterilized regretted that decision and 1% sought sterilization reversal. These authors achieved a 50% term pregnancy rate (113 cases) and found that neither age, parity, nor interval between sterilization and reversal were factors determining successful outcome. Determining factors did include the length of Fallopian tube remaining, the type of previous sterilization, the location of the anastomotic site (isthmo-isthmic anastomosis was best) and the availability of both tubes for reconstruction. Silver² likewise found that the likelihood of a positive outcome was directly proportional to the length of the longest tube and that the mean time (in months) from sterilization to pregnancy was inversely proportional to that length. His success rate ranged from 18% (with tubal length less than 3 cm) to 100% (with tubal length greater than 5 cm). He concluded that so long as there remained greater than 1 cm of tubal ampulla plus fimbria, the only other factors affecting a positive outcome were total tubal length and an accurate anastomosis. Similar findings have been reported from North Carolina by Hulka and Halme.³

Prior to the now-popular bipolar electrocautery and clip sterilization methods, unipolar electrocautery was used. This caused thermal damage both proximally and distally along the tube away from the application site, and good results from attempts to reverse unipolar sterilization were felt to be almost unobtainable. Some authors⁴ did report good results with tubal reimplantation methods, but this technique was quickly replaced by isthmo-cornual reanastomoses. Microsurgical shaving techniques allowed surgeons to dissect back into the uterine cornu to find portions of tube without obvious thermal damage, and Winston⁵ reported pregnancy success rates after isthmo-cornual anastomoses to be equally as good as those obtained after isthmo-isthmic anastomoses (71% vs. 75%). Other authors⁶ have duplicated these findings.

Microsurgical techniques have improved over the years but the broad concepts of emphasizing gentle tissue handling, meticulous hemostasis, careful dissection, and accurate approximation of tissues have remained constant.⁷ Adjunctive therapy such as post-operative use of Dexamethasone and Promethazine⁸ have been changed and modified; the use of prophylactic antibiotics, tubal stents, anti-prostaglandin drugs, and post-operative intraperitoneal Dextran 70⁹ have had varying degrees of success.

We decided to review the results of

our attempts to reverse tubal ligation in our community hospital-based practice.

The Population Studied

During the past seven years 19 patients have come to our clinic requesting reversal of previous tubal interruption surgery. The average age of the patients was 30 years (range 23-37); the mean interval from sterilization to attempted reversal was 6.2 years (range 1-14); and the average parity was 1.5 (range 0-3). The reason almost all of the patients gave for their change of mind was a change in their marital status.

Pre-operative evaluation of each patient included a review of the operative record of the previous surgery, proof of potential fertility (evidence of continuing ovulation and a semen analysis of the new husband), followed by laparoscopy of the pelvis to evaluate the remaining tubal segments. We planned to exclude any patient with tubal segments less than 3 cm long, but all of patients had at least one tubal segment greater than 3 cm, so no patients were denied surgery.

The microsurgical team was always comprised of the same operating room personnel; this greatly facilitated the set up of a fairly complex operation and added to the smoothness of the surgery itself. All gloves were thoroughly washed to remove talc, and continuous irrigation

From Piedmont Obstetrics & Gynecology, 210 13th Ave. Place, NW, Hickory 28601.

with Ringer's lactate solution (no saline) was used as were low wattage bipolar forceps. The tubal segments were aligned and anastomosed whenever possible over a #1 nylon stent that was threaded into the uterus and removed the following morning (after approximately 18 hours). The anastomosis itself was made using 8-0 and 9-0 polyglactin (Vicryl) sutures in a standard two-layer closure. Post-operative care included the instillation of 200 cc of Dextran 70 intraperitoneally, prophylactic antibiotics, and anti-prostaglandins.

Results

To date, 14 of the 19 women (74%) have achieved a total of 16 term pregnancies. There has been a total of 26 conceptions in 16 women (84%), including 6 abortions (23% of conceptions) and 6 ectopic pregnancies (23%). These good results were obtained despite the presence of many other mitigating factors including oligo-ovulation, endometriosis, oligospermia, and previous oophorectomy (2 patients). All six ectopic pregnancies (in 5 patients) were removed laparoscopically; four patients had a subsequent term pregnancy and one has had a spontaneous abortion.

Three women have not become pregnant. They have been reevaluated by laparoscopy and hysterosalpingogram and found to have tubal patency on at least

one side; one of these patients was the oldest in the series (age 37) and another had only one tube amenable to reconstructive surgery, the other tube having severe intraluminal fibrosis.

As expected, Hulka clips and unipolar electrocautery techniques caused the least tubal damage. Tubes treated in this way lent themselves most readily to isthmo-isthmic anastomosis with fairly good surgical outcomes. Five patients who had previous unipolar electrocautery sterilizations had at least one isthmo-cornual anastomosis and four of them have conceived. The fifth patient, who had total obliteration of one tubal lumen by the electrocautery, had an isthmo-ampullary anastomosis performed on the "good" tube that remains patent, but she remains infertile with problems of anovulation, hostile cervical mucous, and oligospermia.

Comments

Post-reconstruction, our patients stay in the hospital for 1 to 2 days. In our hands this is not yet an out-patient procedure, but it is a much less expensive means of achieving fertility than is *in vitro* fertilization or other extra-corporeal techniques.

The specialty of OB/GYN has become so fragmented by specialty boards that some of us feel compelled to refer nearly every complicated case to boarded subspecialists in GYN oncology, GYN

infertility, perinatology, and perhaps, in the future, even routine GYN surgery! Our series is testimony to the fact that specialized surgical procedures can be performed at a community hospital level with a high degree of success. A level of surgical dedication, preparation, and attention to detail is required on the part of the surgeon and the surgical team, but with that dedication and commitment comes success. A team approach that includes the patient, the surgeon, and the OR personnel is the key to the success of this procedure.

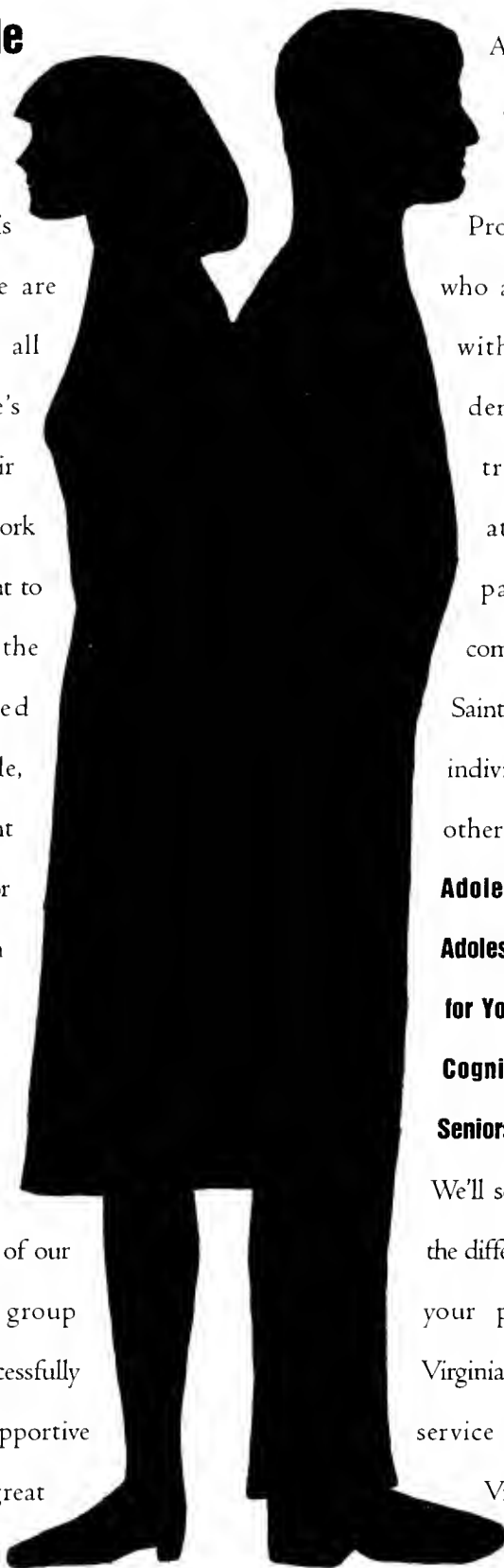
Finally, our goal would be that adherence to timely indications for the initial sterilization might eliminate the need for reversal at all. Abraham et al,¹⁰ comparing the psychological profiles of 32 women with 53 controls, found, as did we, that change in marital status was responsible for the most reversal decisions. Since most of the women requesting reversal fitted "feminine" stereotypes, Abraham et al recommended that the initial sterilization not be done until the woman has considered her feelings, is aware of its implications, and has made the decision herself. Physicians should discourage requests for sterilization when a marriage is not stable and should not perform the surgery post-partially or post-abortally unless the patient requested the procedure and was thoroughly counseled prior to the pregnancy. □

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Enhancing Adherence with Mammography Through Patient Letters and Physician Prompts

A Pilot Study

Suzanne E. Landis, M.D., M.P.H., Stephen D. Hulkower, M.D., and Scott Pierson, M.S.P.H.

Breast cancer is the leading cause of premature death due to cancer in women.¹ It accounts for 18% of cancer deaths and 28% of all newly diagnosed cancers in women.² In 1989 an estimated 142,000 new cases of breast cancer occurred in the United States, and 43,000 women died of this disease.²

Screening tests for breast cancer include clinical examination of the breast, breast self-examination, and mammography. The sensitivity of mammography (its ability to detect cancer when cancer is present) is estimated to be as high as 87% for women over 50 years of age, while specificity (ability to exclude cancer when cancer is absent) is between 94% and 99%.³ There is convincing evidence from New York (the Health Insurance Plan study), Sweden ("two county study"), and the Netherlands to demonstrate that mammographic screening reduces mortality from breast cancer in women aged 50 and over.^{4,5}

Despite the proven efficacy of mammograms in preventing unnecessary death, women continue to underutilize this screening procedure. Only about 30% of women have undergone mammographic screening, and among minority

women as few as 16% report ever having had a mammogram.⁷⁻¹² Significant barriers to utilization include both physicians who fail to stress the importance of mammograms or who do not schedule examinations and patients who are concerned about cost, about inadequate reimbursement from insurance companies, and about perceived radiation risk, pain, and ineffectiveness of the test itself.^{11,13-16}

Practice-based interventions (prompts to physicians or written reminders to patients) enhance compliance with other preventive services such as influenza immunization and pap smears.^{17,18} Microcomputer-generated reminders have successfully enhanced compliance with mammographic screening in two university-based family practice residency practices.^{12,19} Postcards and patient letters have been used to encourage women to request that their primary care physician order a mammogram, and to remind women to keep scheduled appointments for screening mammograms.^{19,20} We report here the results of a randomized, practice-based pilot study to determine whether physician prompts or patient letters or both would enhance compliance with mammography among inadequately screened patients. Our study differs from those previously reported by targeting inadequately screened women and by utilizing a pa-

tient reminder letter, sent after the office visit, that included a prescription order for the mammogram and thus eliminated a visit or call back to the primary care physician.

Methods

Patient Selection. This pilot study was conducted in the Mountain Area Family Health Center. In this Asheville-based practice, 18 family practice residents and 8 faculty provide care for approximately 16,000 patients. Female patients aged 50 to 70 years were considered eligible for the study if they had been seen at least twice during the preceding two years and had not had a mammogram in the previous year. We excluded women who had a history of breast disease (fibrocystic breasts, previous breast biopsy, or breast cancer) recorded in the chart.

From January 22, 1990, until May 30, 1990, we reviewed the charts of all 50- to 70-year-old female patients as they arrived for a visit with their usual physician. A study assistant recorded date of birth, race, name of insurance company, assigned physician, date of first and last visit to the Center, presence of breast disease, and date of mammogram on a chart abstraction form. Patients who had no mammogram report from the prior year were eligible for the study.

From the Mountain Area Health Education Center, 501 Biltmore Ave., Asheville 28801-4686.

During the study period, 162 potentially eligible women had their charts reviewed. Eight (5%) of these women had a history of breast disease and were excluded. Thirty-two (21%) had had a mammogram in the past year and were also excluded. Of the remaining 122 eligible patients, 38 had physicians who were assigned to receive a "Doctor Prompt" and 84 had physicians who were not to receive such a reminder ("No Doctor Prompt"). The randomization resulted in equal numbers of physicians in both the "Doctor Prompt" and "No Doctor Prompt" groups, but there were unequal numbers of patients in these two groups due to the large number of eligible patients seen by one physician in the "No Doctor Prompt" group. In the "Doctor Prompt" group, 24 patients received a Patient Letter, while 14 patients in this group received a Placebo Letter. In the "No Doctor Prompt" group, 41 patients received a Patient Letter recommending a mammogram and 43, the Placebo Letter.

Six faculty, six first-year residents, seven second-year residents, and five third-year residents participated in the study (two of the faculty were authors and did not participate). Nine of the residents were women.

Interventions. Physicians were randomly assigned to the "Doctor Prompt" or "No Doctor Prompt" groups. Depend-

ing on randomization group, all of a given physician's patient charts either had or did not have the "Doctor Prompt," thus reducing the positive cross-over effect that might have occurred if some of a doctor's patient charts had a Prompt and others did not. Physicians in the "Doctor-Prompt" group received the patient's chart with an attached, computer-generated card stating that the patient was eligible for screening mammography and had had no mammogram in the last year. The card remained on the chart until our office received a mammogram report or the physician indicated that they no longer wanted the Prompt or that the patient had refused mammography.

In addition, patients within the Doctor Prompt and No Doctor Prompt groups were randomized to receive either a Patient Letter or a Placebo Letter. The Patient Letter, signed by one of the authors (SDH), stated that the Center encouraged all female patients aged 50 to 70 years to have annual screening mammograms. It also stated that our records showed the patient had not had a mammogram in the last year and included a prescription for one; patients could call the radiology center directly to schedule an appointment. The Placebo Letter was a patient satisfaction survey, mailed the day of the patient visit. Patients received one letter no matter how many times they visited the practice within the study period.

The factorial design protocol resulted in four randomized groups of patients: 1) Doctor Prompt and Patient Letter; 2) Doctor Prompt and Placebo Letter; 3) No Doctor Prompt and Patient Letter; and 4) No Doctor Prompt and Placebo Letter. The outcome of interest was whether the patient obtained a mammogram (defined by our practice as receiving a mammogram report within three months of the date the physician or patient was prompted).

Analyses. We used descriptive statistics to summarize patient characteristics. Differences between intervention groups were compared using chi square statistics for categorical data and analysis of variance (ANOVA) for continuous data (calculated with EPI INFO software).

Results

As a group the participants had a median age of 62.5 years; 83% were white; 67% had insurance of some type; and 15 of the 122 women (12%) received mammograms during the study. Study groups showed no significant differences in median age or insurance status (Table 1). The Doctor Prompt/Patient Letter group had significantly more ($p = 0.03$) black patients (38%) than the other three groups (7%, 12%, 14%, respectively).

Six of 24 patients (25%) in the Doctor Prompt/Patient Letter group received mammograms compared to only one of 43 (5%) in the No Doctor Prompt/Placebo Letter group ($p = 0.07$, Table 1). The other intervention groups had intermediate rates between these extremes, but the small numbers in this pilot study did not give statistical significance for the different rates in these groups.

Women receiving mammograms did not differ by age, race, or insur-

Table 1. Participant characteristics by intervention group

		Intervention group			
		1	2	3	4
Doctor Prompt?		Yes	Yes	No	No
Patient Letter?		Yes	No	Yes	No
Number of Patients		24	14	41	43
Age (median, in years)		65.5	63.5	63	61
Race*	Black	9 (38%)	2 (14%)	5 (7%)	5 (12%)
	White	15 (62%)	12 (86%)	36 (93%)	38 (88%)
Insurance	Yes	21 (88%)	9 (64%)	26 (63%)	26 (60%)
	No	3 (13%)	5 (36%)	15 (37%)	17 (40%)
Mammograms**	Yes	6 (25%)	1 (7%)	6 (15%)	2 (5%)
	No	18 (75%)	13 (93%)	35 (85%)	41 (95%)

* $p = 0.03$

** $p = 0.07$

Table 2. Participant characteristics by mammogram status

		Did patient have mammogram during study?	
		Yes (N = 15)	No (N = 107)
1. Age:	62 years or less	7 (46%)	51 (48%)
	63 or older	8 (54%)	56 (52%)
2. Race:	White	12 (80%)	89 (83%)
	Black	3 (20%)	18 (17%)
3. Health Insurance:	Yes	10 (67%)	71 (67%)
	No	5 (33%)	35 (33%)
4. Intervention Group*:			
	1) Doctor Prompt/Patient Letter	6 (40%)	18 (17%)
	2) Doctor Prompt/Placebo Letter	1 (7%)	13 (12%)
	3) No Doctor Prompt/Patient Letter	6 (40%)	35 (33%)
	4) No Doctor Prompt/Placebo Letter	2 (13%)	41 (38%)

* P = 0.07

ance status from those not receiving mammograms (Table 2). However, 40% of women who obtained mammograms had received a Patient Letter and their physicians a Doctor Prompt although this group (Group 1) represented only 20% (24 + 122) of the total study population. Likewise, patients whose doctor did not receive a Prompt and who did not receive a Patient Letter (Group 4) represented only 13% of women getting mammograms but 35% (43 + 122) of the study group.

Discussion

In our practice, like other residency-based practices,¹⁰ about 20% of active female patients between 50 and 70 years of age have had a mammogram in the prior year. Among patients who had not had a recent mammogram, we were able to increase the proportion who received a screening mammogram from 5% in the No Doctor Prompt/Placebo Letter group (usual care)

to 25% by using both a Doctor Prompt and a Patient Letter.

The type and availability of health insurance did not affect adherence to mammographic screening recommendations. This may, in part, reflect the widespread contemporary refusal of almost all insurance companies to reimburse for mammographic screening.

There are limitations to our study. The small sample size in the Doctor Prompt/Placebo Letter group (N = 14) limited our power to detect improvement in adherence with mammography recommendations. Nor could we carry out subgroup analyses, such as whether year of residency or faculty status impacted adherence.

Since this pilot study was completed at only one clinical site, physicians in the No Doctor Prompt group might have become aware of the study and increased their mammogram prescribing practices. Nor is our residency-associated family practice center necessarily representative of other private practices where continu-

ity of care with the patient's own physician is easier to maintain.

Barriers to screening such as pain, inconvenience, cost, and misperceptions of efficacy by patients were not addressed in this pilot study. Attention to these barriers through insurance reform, reduction of charges to patients, alterations of social norms to support routine screening mammography, and provision of medical and mammographic services in easily accessible and culturally sensitive health care settings will help increase the overall compliance rate for mammography to a more acceptable

range of 80% to 90%.^{7,13,15,16,21}

Despite any limitations, however, our study has important implications. In the initial cohort of 154 women, 32 had already had mammograms. If all of the remaining 122 study subjects had received both of the Doctor Prompt and Patient Letter interventions and if we assume that 30 of them (25%) would comply with mammographic screening recommendations, then the overall compliance of women in our practice would improve to about 40% [(32+30)/154]. This is a marked increase from our baseline rate of 21%, but most physicians would consider it a still unacceptably low rate of compliance for a screening procedure that so effectively reduces breast cancer mortality. We plan to routinely use both Doctor Prompts and Patient Letters at our newly constructed office and to monitor adherence in a longitudinal fashion. □

Acknowledgment: The authors thank research assistant Dana McGraw for her invaluable assistance.

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Mediation of Medical Malpractice Claims

Robert A. Phillips

Editor's Note: In preparing this article for publication, we invited three North Carolina attorneys to comment on the subject of mediation. They are: Michael M. Lakin of Durham, Julian D. Bobbitt, Jr., of Raleigh, and Grover C. McCain, Jr., of Chapel Hill. Their comments follow.

Mediation is a process whereby a neutral person acts to encourage the resolution of a dispute between two or more parties. The concept of using a neutral third party to step in and help others resolve a dispute has been around for a long time, but its most recent application takes the form of mandated mediation to settle pending lawsuits (court-ordered mediation), and mediation of claims before a lawsuit is filed (pre-litigation mediation).

The North Carolina legislature recently enacted GS 7A-38 establishing a pilot program of mediated settlement conferences for Superior Court cases. It is currently being implemented in 13 counties (Halifax, Cumberland, Bladen, Brunswick, Columbus, Chatham, Orange, Stokes, Surry, Guilford, Forsyth, Haywood, and Jackson). If this program is successful, it will probably be enacted statewide by 1995.

Court-Ordered Mediation

In court-ordered mediated settlement conferences, the judge may order a case to mediation and appoint a certified mediator, or the parties may select a person to act as mediator. All parties and insurance representatives are required to attend the mediation conference, with full authority to settle.

Mr. Phillips is an attorney and mediator. His address is P.O. Box 995, Burnsville 28714.

The mediator in these conferences does not make decisions as does an arbitrator or judge, but rather helps to facilitate negotiations between the parties. The mediated settlement conference usually begins with an introduction and explanation of the process by the mediator. All sides present their views of the case and then discuss and clarify the issues. The parties, at some point, separate and the mediator acts as a "go-between," facilitating the negotiation of the interests of the parties. When

settlement is reached, the parties are encouraged to enter into a written, judicially-enforceable agreement before leaving the conference.

Most mediated settlement conferences last from three to four

hours and have a settlement rate of 65% to 85%, depending on the type of case. As a general rule, the more complex and more difficult a case will be to try, the more likely it is to settle.

In medical malpractice cases, mediation is especially useful for the following reasons: 1) it is private; 2) it is fast; 3) it is economical (\$300 to \$400 per party); 4) the settlements reached are final and non-appealable; 5) it is easy to prepare for; 6) it is confidential (what is said is not admissible as evidence); 7) it is scheduled at the convenience of the parties; and 8) the settlement is controlled by the parties directly concerned with the case, who are knowledgeable about its medical and legal aspects.

Mediation offers numerous benefits to physicians against whom a claim is made: 1) it allows the physician more control

"A pilot program of mediated settlement conferences for Superior Court cases...is currently being implemented in 13 counties. If this program is successful, it will probably be enacted statewide by 1995."

and management over the resolution of the dispute; 2) each side gets to see the other's best offer or demand and can then decide whether to settle or to litigate; 3) it prevents the unlimited exposure and uncertainty of trial; 4) it avoids the expenses of trial preparation and of the trial itself; 5) it allows the realities of medicine and medical practice to greatly influence the outcome; 6) it drastically decreases the time lost from medical practice in resolving a malpractice claim; and 7) it disposes of frivolous claims before too much time and money are invested.

Pre-Litigation Mediation

An even more innovative approach to the settlement of malpractice claims is pre-litigation mediation in which mediation is initiated as soon as a claim arises, but before a lawsuit is filed. It is sometimes encouraged by an insurance carrier or a hospital claims manager. This method of claims management is in its infancy and is still in search of a final format. One possible means of initiating this process is to make it part of the standard patient consent form, so that the patient agrees to submit any potential claims to the formal mediation process before a

lawsuit can be filed. Architects and other professionals are using this method to resolve potential disputes.

Pre-litigation mediation's early attention to settlement provides even greater benefits than court-mandated mediation. The settlement conference is totally private and confidential, since no lawsuit has been filed. The settlement terms can also be made confidential. The time spent and expense incurred are reduced, since depositions and other trial-related procedures are avoided. Meritorious claims can be settled privately and expeditiously. An extensive early view of the case gives a clearer picture of potential exposure and a chance to mitigate damages by appropriate corrective treatment.

Conclusion

There is virtually no "down side" to mediation of a medical malpractice claim. Even when the conference doesn't result in settlement, the parties gain a more realistic picture of the dispute and a better understanding of the potential risk involved in resorting to litigation. □

Invited Comments

Michael M. Lakin, Attorney at Law
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North Carolina judges who hear medical malpractice and other trials involving substantial damages are concerned about the growth in their dockets, in the quantity of litigation. This growth results in a need for more judges, courtrooms, and administrative services. Many judges hope that the pilot program of mediated settlement conferences will reduce this demand by helping cases to be settled earlier and more often, with less involvement by the judge in pre-trial disputes and a reduced likelihood of cases proceeding to trial. It is expected that in the judicial districts participating in the pilot program, the senior resident superior court judge will refer almost all cases for mandatory mediation. Since the disputing parties pay the mediator's fees under the pilot program, the entire mediation system is conceived as operating at no cost to the taxpayers.

A review panel appointed by two state agencies, the Administrative Office of the Courts and the Institute of Government, will evaluate the pilot program. The evaluation will likely consider the settlement rate of cases referred to mediation, examine when settlement was reached in the course of the mediation, and compare these data to information from a control group of cases that proceed through the ordinary litigation process. According to the Administrative Office of the

Courts, the ordinary process results in approximately 95% of North Carolina cases being settled before trial. We do not yet know the settlement rate for mediation conferences in our state. The review panel is expected to survey parties, attorneys, judges, and mediators to obtain their views as to the virtues and deficits in the mediation program.

The review panel's conclusions will be reported to the legislature in 1995 or afterward, and the legislature will decide whether to adopt a permanent, statewide program of mandatory mediated settlement conferences for superior court litigation. The review panel will try to evaluate the quality of the mediation in the various cases, as well as whether the pilot program saves money for the litigants and the state.

The quality of mediation provided during the pilot program will depend on the abilities of the individual mediators. Under rules recently adopted by the North Carolina Supreme Court, a certified mediator must be a member of the North Carolina bar with at least five years of legal experience, must take an approved, 40-hour mediation training course, must pass an exam based on the training course, must observe two mediated settlement conferences, and must be of good moral character. There is sufficient excitement among some members of the bar about the potential of mediation and other alternate dispute resolution mechanisms that the pilot program may attract a number of capable and energetic mediators. On the other hand,

the requirements for certification as a mediator are relatively low, and it is impossible to predict that the quality of mediation in the pilot program will be high.

Will the pilot program save money for litigants? The review panel's conclusions in 1995 will give us some answers to this question, but here are some preliminary thoughts. The mediation of a case will be economical if it is successful in forestalling a long, drawn-out battle that culminates in an expensive trial. What if the mediation does not settle the case? The parties may still feel that they have gained a more realistic picture of the dispute, and that the unsuccessful mediation was worthwhile. On the other hand, they may feel that they have been required to go through a useless exercise, at significant cost. What might the typical mediation process cost the parties? The mediation process involves: a) a fee paid to the mediator,

which may be \$250 to \$400 per party; b) a fee paid to the party's attorney for the time spent participating in the mediation, perhaps \$500 or more if the conference is resolved in four hours, perhaps double that if the conference is prolonged; c) a fee paid to the party's attorney for time spent in preparation for the mediation; and d) the cost of the party's time spent in attending the mediated settlement conference. This last component is worth noting. Under the pilot program, the plaintiff and defendant must attend all mediated settlement conferences, or be subject to sanctions. For doctors involved in medical malpractice actions, this may be a disadvantage of mediation. If the case settles at the conference, doctors will probably feel that their presence was worthwhile, but if the case continues after the conference, doctors may feel that valuable time was lost in a fruitless exercise. □

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Alternative dispute resolution for medical malpractice cases holds great promise for North Carolina. Through private experimentation by parties and through legislated study, a broad array of techniques are being scrutinized within the state. None are perfect. Nor is the technique of mediation perfect. It is reputedly most successful when the parties simply need to sit down in the same room, look one another in the eye, and be heard. On the other hand, the non-binding, inexpensive processes that Mr. Phillips discusses have been alleged to give rise to an even higher frequency of claims than exists now. Really cynical observers think that mediation merely offers the plaintiff a "sneak preview" of the doctor's case.

In any event, alternative dispute resolution of medical malpractice cases is coming to North Carolina. I think that mediation will have a significant place, perhaps as an option. There will be better, more efficient, and less expensive methods to help solve the problems of medical malpractice but, as of yet, there is no "panacea." □

Grover C. McCain, Jr., Attorney at Law
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Mr. Phillips' article, written from the viewpoint of a mediation service, is a compilation of arguments from those who favor mediation and is fairly straightforward. However, readers should be aware the mediation works only when both sides wish to mediate their case. If one or both parties do not favor mediation as a means of resolving their suit, then both time and money can be wasted in the mediation process. Mediation is only a method of settling a case, and not all cases are amenable to or should be settled. Some parties desire their "day in court." □

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Prudent Prescribing

Prescribing Suggestions for Physicians

Lyndon K. Jordan, III, M.S. IV,¹ and Laurie O. Jordan, M.D., R.Ph.²

"A significant problem facing patients throughout the country is the rising cost of medical care. In addition to the physician's fees and laboratory charges of a routine office visit, patients may face an even greater bill from the pharmacy. There are several ways that physicians can help."

Ensuring that drug therapy is cost effective remains a continuing challenge for all physicians. According to government statistics, expenditures for prescription drugs and medical sundries in this country will reach \$65 billion by 1995—a 38-fold increase since 1950 (Figure 1). In 1989, \$604.1 billion was spent on health care in this country. Medications accounted for almost \$45 billion, nearly 1% of the gross national product!¹ From 1982 to 1988, medical care costs increased at double the rate of the consumer economy, with prescription drugs rising the fastest.²

As increasing attention focuses on the rising cost of medical care, it is clear that informed selection of drug therapy is vitally important. Physicians are obligated to offer the most appropriate medications and to save their patients money when it can be done without compromising medical care. We review several ways physicians may help.

From the ¹Duke University School of Medicine, Durham, and the ²Department of Anesthesiology, Duke University Medical Center, Durham 27710.

Factors That Influence Prescribing Habits

Several factors influence physicians' prescribing habits:

- Pharmaceutical companies spend millions of dollars marketing their products. They give catchy names to these medications so that they will be remembered. Pharmaceutical companies provide physicians with free gifts, meals, and at times, entertainment in attempts to give a new drug name recognition.

- Medications may be prescribed purely by habit. While there is merit in prescribing medications backed by 20 years of experience, it is important to keep abreast of up-to-date recommendations about prescription indications.

- Sometimes drugs such as antibiotics are prescribed in response to patient expectations. Despite the pressures of patient requests, we should avoid giving antibiotics as a kind of "placebo" that

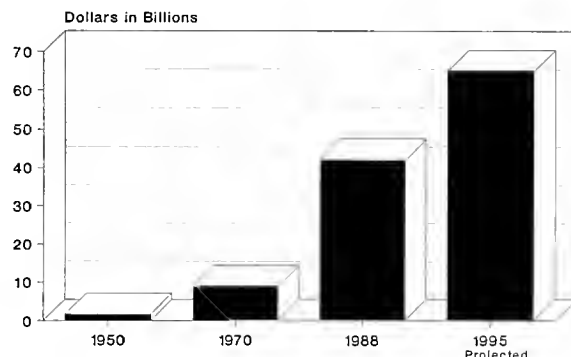


Figure 1: U.S. expenditures on drugs and medical sundries^{1,2}

Table 1. International comparison of prescribing rates³

Country	Scripts/Pt/Yr
USA	16.6
Italy	11.3
(W) Germany	11.2
France	10.1
Spain	9.6
New Zealand	8.5
Australia	7.7
Sweden	4.7

may hasten an office visit.³

• There are national trends regarding the propriety of prescribing. As Table 1 illustrates, physicians in the United

States are the most prescribing doctors in the world.

Generic Drugs vs. Name Brands

The Federal Trade Commission reported that the American public saved \$236 million in 1985 by purchasing generic medications.⁴ The Drug Price Competition and Patent Term Restoration Act of 1984 lessened restrictions on the production of generic medications. Nevertheless, there has been concern surrounding the safety and efficacy of these drugs, as well as debate regarding the actual savings realized through the use of generic prescribing. Generic drugs, on average, are cheaper for the pharmacist and the patient.^{5,6} However, the difference is often small for most medications. In fact, it is not uncommon for a generic drug to cost more than the name brand. Pharmacists may profit more from filling the generic prescription because the mark-up and profit tend to be higher for generic drugs than for the name brand. On the other hand, generic preparations becoming available because of the expiration of patent or market exclusivity rights may offer a 30% to 70% reduction in price. Generic preparations available in 1992 include diltiazem (Cardizem), cefaclor (Ceclor), piroxicam (Feldene), metoprolol (Lopressor), nifedipine (Procardia), and atenolol (Tenormin). Next year triazolam (Halcion), naproxen (Naprosyn), cromolyn (Intal), gemfibrozil (Lopid), mexilitine (Mexitil), and alprazolam (Xanax) may be available as cheaper generic medications as well.¹²

Drug effectiveness is the crucial element in the decision between a generic and a name-brand medication. Substitutions may be appropriate in some cases, but not in others. Medications that require strict and specific therapeutic blood levels are not good drugs for substitution. Most physicians consider hormonal agents, anti-seizure medications, and various anti-arrhythmic cardiac agents to be among these drugs. Furthermore, since many medications may be composed of

Table 2. Commonly prescribed medications

Antihypertensives:

Medication	Qty.	Nat'l Chain	Indep. Pharm	AWP*
Furosemide 40mg	30	\$ 3.49	\$ 6.69	\$ 0.55
Lasix 40mg	30	\$ 5.69	\$ 9.93	\$ 4.35
Hydrochlorothiazide 50mg	60	\$ 3.29	\$ 7.41	\$ 1.21
Hydrodiuril 50mg	60	\$16.89	\$19.61	\$11.65
Prazosin 1mg	90	\$11.89	\$20.63	\$21.42
Minipress 1mg	90	\$36.59	\$37.84	\$31.86
Propranolol 40mg	90	\$ 8.59	\$12.12	\$ 7.65
Inderal 40mg	90	\$32.59	\$60.63	\$40.27
Spironolactone 50mg	60	\$17.99	\$ 9.87	\$ 3.82
Aldactone 50mg	60	\$39.79	\$49.95	\$33.75
Verapamil 80mg	90	\$12.69	\$17.13	\$19.35
Calan 80mg	90	\$31.49	\$54.84	\$35.59

Antibiotics:

Medication	Qty.	Nat'l Chain	Indep. Pharm	AWP*
Amoxicillin 500mg	30	\$ 9.99	\$20.24	\$ 9.96
Amoxil 500mg	30	\$ 9.99	\$20.24	\$12.12
Augmentin 500mg	30	\$56.29	\$70.28	\$67.70
Cephalexin 250mg	40	\$10.29	\$12.21	\$17.20
Keflex 250mg	40	\$45.69	\$50.64	\$44.92
Ceclor 250mg	30	\$50.69	\$58.26	\$52.65
Ceftin 250mg	20	\$50.09	\$58.26	\$55.32
Erythromycin 250mg	40	\$ 7.79	\$11.87	\$ 4.49
E-Mycin 250mg	40	\$ 7.79	\$16.86	\$ 9.62
Penicillin VK 250mg	40	\$ 5.79	\$ 8.90	\$ 2.38
V-Cillin 250mg	40	\$13.39	\$14.77	\$ 7.88
SMX/TMP 20mg	20	\$ 4.89	\$11.85	\$ 2.92
Septa DS	20	\$25.49	\$30.81	\$19.93

Other commonly used medications:

Medication	Qty.	Nat'l Chain	Indep. Pharm	AWP*
Ortho-Novum 777		\$17.59	\$22.39	\$20.35
Lo/Ovral		\$14.99	\$24.53	\$21.36
Zantac 150mg	60	\$72.49	\$95.52	\$88.44
Tagamet 400mg	60	\$61.09	\$79.59	\$77.55
Ibuprofen 800mg	90	\$10.39	\$10.05	\$19.71
Motrin 800mg	90	\$22.09	\$46.02	\$31.21
Naprosyn 500mg	60	\$55.99	\$79.32	\$63.62

*AWP = Average Wholesale Price. Prices were compared between a national chain pharmacy and an independent community pharmacy in North Carolina.

only 5% active agent, 95% of a generic tablet's content may differ significantly from its name-brand counterpart.⁷ Although most medications have been carefully screened, physicians should be mindful of these factors.

The Cost of Medications

Patients decide which pharmacy to patronize. However, it helps to know some of the reasons for cost variability of prescribed medications from pharmacy to pharmacy. We studied the sales records of a privately owned community pharmacy in North Carolina and found that patients paid an average of \$30 per prescription in April 1992, a 50% increase over the cost in April 1987. Table 2, opposite, compares the costs of popular medications among independent community pharmacies, national chains, and wholesale suppliers.

Where Patients Purchase Medications

Independent and chain pharmacies. Many patients will select an independent community pharmacy for service, such as convenient billing options, helpful and available pharmacists, delivery, etc. Other consumers will buy from a national chain for actual or perceived savings.

Many pharmacies employ complex marketing strategies. Some tactics include "loss leaders," selling popular medications (oral contraceptives, analgesics, etc.) at wholesale or even below wholesale prices. Other medications and products are then sold at higher prices and generate greater profit for the pharmacy.

Mail-order pharmacies. Mail Pharmacy Services fill nearly 90 million prescriptions a year with anticipated sales of \$5 billion dollars in 1993, primarily to patients obtaining medications through the Veterans Administration, the American Association of Retired Persons, corporate employers, and the government.⁸

Medications may even be ordered through personal computer information services offering an "on-line pharmacy." Approximately 100 different medications are offered by mail at Sears stores nationwide. These services claim a 5% to 50% savings in prescription cost.⁸

Mail Pharmacy Services generally do not provide medications for acute problems. Instead these services target patients who require chronic or maintenance medications, which represent more than two-thirds of the prescription drug market.⁸ When dealing with mail-order pharmacies, patients must purchase large quantities of the medications. In addition, contact with the pharmacist is replaced by a toll-free telephone call.

"Medications may be cheaper if they are dispensed in pre-packaged lots...such as quantities of 100. Pharmacists may be able to discount those medications when they do not have to count and repackage them."

Dispensing Fees

As part of their profit-maximizing strategy, pharmacies add dispensing fees to the patient's charge for medications. Most pharmacies use a sliding scale of fees, but an examination of medication pricing at a university medical center in North Carolina is instructive. It adds a flat fee of \$7.50 to the Average Wholesale Price (AWP) for filling each prescription. For example, if the wholesale cost of 30 tablets of a medication is \$20, then the prescription charge would be \$27.50. Prescribing in the appropriate quantity is vital. A prescription for one pill of spironolactone would cost \$7.56, calculated

by the \$7.50 dispensing fee plus 6 cents for the AWP of spironolactone. Obviously, it is much cheaper for the patient to buy in larger quantities. Instead of \$7.56 for a quantity of one pill, the patient would have to pay only \$13.86 for 100 pills. Furthermore, medications may be cheaper if they are dispensed in pre-packaged lots as received from the manufacturer, such as quantities of 100. Pharmacists may be able to discount those medications when they do not have to count and repackage them.

Pharmacies associated with teaching institutions have another advantage in the pricing strategy. These hospitals may obtain medication at "bid prices," which may be substantially lower than the AWP. For example, the AWP for 25 mg of diphenhydramine (Benadryl) from Parke-Davis is \$121.90 per 1,000 tablets; however, the university pharmacy may purchase the same product for \$7.65 per 1,000 tablets. It has been suggested that pharmaceutical companies employ this marketing strategy to engender prescribing habits of resident physicians at the institution. Whatever the reason, this pricing strategy sometimes results in cost savings that can be helpful to patients.

Prescription Payments by Third-Party Payers

Third-party coverage of prescription payments is increasing. In 1989 more than 700 million prescriptions were filled under third-party coverage. Medicaid accounted for 18.9% of those prescriptions.² In response to these Medicaid costs, several states have imposed prescription caps.¹⁰ It is estimated that by 1995, more than 60% of prescriptions will be covered by third parties.² In many third-party programs, patients pay a fixed amount (co-payment) for their medication, regardless of the pharmacy they choose.

Most insurance policies provide for coverage (or partial coverage) of prescribed medications, but they will not pay for over-the-counter medications, even one that might work as well. Many patients will ask for the prescription brand

perhaps because of their belief that they will save money and their faith in the "power of prescription."

Tips for Improved Prescribing

✓ **Minimize medication.** It is useful to keep in mind that a change in lifestyle may be more effective than prescribing a medication. Enlist the patient's help in using a cost-effective, non-medication alternative when possible.

✓ **Encourage compliance.** Be mindful of possible side effects and other issues that affect patient compliance and safety. Patients may need to be reminded about the dangers of overdosage and the importance of childproofing the medicine cabinet. Encourage patients to contact your office with questions about prescribed medications. Provide patients with phone numbers for local or regional poison control centers (800-672-1697) so that they can obtain emergency overdose information about medications or household products.

✓ **Know medication costs.** When appropriate, it is helpful to prescribe generic medications, since they usually save patients money. In general, capsules are more costly than tablet forms, and liquid suspensions are more costly still. Encourage patients to comparison shop at pharmacies; feedback from patients about economical purchasing is valuable.

✓ **Enlist the patient's help.** Ask patients to help decide purchase quantities and tailor amounts to accommodate the patient's insurance payment policies. Since patients may receive medications from multiple doctors, encourage patients to bring all of their medications to their appointments. Reviewing the medications will help clarify patient instructions and will give clues about patient compliance.

✓ **Know community resources.** Local health departments sometimes provide free or markedly reduced medications (such as isoniazid), birth control pills and contraceptives, and immunizations.

✓ **Know the pharmacist.** Knowledgeable pharmacists can help patients save money. In a study at the Francis Scott Key Medical Center in Maryland, a pharmacist helped save nearly \$24,000 during a 91-day period on a 12-bed medical ICU by teaching cost-reducing principles.¹¹

In the out-patient setting, the pharmacist's computer may be able to construct a list of all of the patient's current medications and track and evaluate drug interactions, contraindications, and cost effectiveness. Computerized records can monitor a patient's compliance, a constant struggle for physicians.

✓ **Utilize pharmaceutical company resources.** Some pharmaceutical companies may supply medications for particularly needy patients. Ciba-Geigy offers a Patient Support Program that sup-

plies free medications to indigent patients (908-277-5849). Similarly, Searle's Patients In Need program supplies various cardiovascular medications free to needy patients (800-542-2526). Pharmaceutical representatives may be able to provide patients with free educational materials along with any medication coupons or rebates. For more information or for a directory of these programs, call the Pharmaceutical Manufacturers Association at 800-PMA-INFO.

✓ **Know thyself.** It is helpful when doctors monitor and understand their prescribing habits. By keeping abreast of current medical information and products we can minimize unwarranted bias in the medications we prescribe. Physicians are often the patient's first, last, and only advocate, and therefore are in the invaluable position of helping the patient to the most effective treatment at the least expense. □

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Health Watch

VOLUME 53 / NUMBER 11 / NOVEMBER 1992

Prescription Drug Use

PRESCRIPTION MEDICINES: DID YOU KNOW...?

Lynn A. Rose, MPH

Brenda M. DeVellis, PhD

Timothy J. Ives, PharmD, MPH

In an ongoing study, healthcare professionals are asked to list issues they feel are important for preventing problems related to prescription medicines. Many of the professionals interviewed stated that you, the patient, need to know the following information so that you can be a more active part of your healthcare team.

Why take prescription medicines?

Prescription medicines are appropriate for use in many situations. One use is to help people recover from illnesses. Another is for the treatment of a health condition so that other more severe health conditions will not occur, as in the case of treating high blood pressure to prevent a stroke. Prescription medicines may be used to control symptoms associated with non-life threatening conditions such as back pain or they may be used to help people function better when they have a chronic illness such as arthritis.

Some health conditions such as infections, may need to be treated with prescription medicines for a short pe-

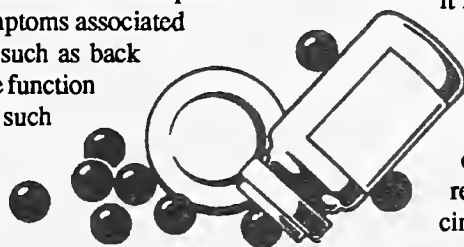
riod of time. Other conditions such as ulcers, may require long-term treatment. Some health conditions such as high blood pressure require prescription medicines indefinitely.

Prescription medicines may enhance the quality of life and well-being of the patient when used properly. However, when misused, these same medicines may be ineffective or harmful.

Your physician and prescription medicines

After evaluating your medical condition your physician may or may not choose to treat it with a prescription medicine and

it is important to remember that not every visit warrants a prescription. There are effective treatments other than prescription medicines for many conditions. For example, some patients recover from a painful back injury through rest alone and never need strong pain medicine.



Discuss with your physician alternative treatments that do not include medications. Should your physician decide that it is in your best interest for you to take prescription medicines, your physician needs complete and accurate information about all of the medicines you are taking and about your medical history. This information will help insure that the medicine the physician chooses to prescribe will be the best one for your overall situation.

Give your physician a complete list of all medicines you are taking or carry the medicines in their containers with you to your physician appointment. Remember that over-the-counter medicines are *medicines*. Over-the-counter medicines could react with other medicines you are taking and cause all of the medicines to be ineffective or even harmful. Therefore, it is important for you to include over-the-counter medicines as well as home remedies, alcohol and tobacco use on your list.

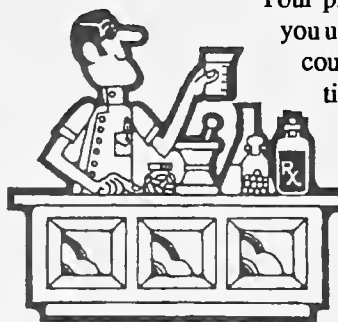
Because many physicians specialize and only treat certain illnesses or medical problems, you may visit more than one physician. All of your physicians need to have complete and accurate information about any medicines you are taking. This information will help prevent any one physician from unknowingly prescribing medicines that you should not take. With knowledge of your other medications, your physician will prescribe a medicine that you can take safely along with those prescribed by other physicians. In some cases, your physician may feel that medicines you are already taking are sufficient and your physician will not need to prescribe any additional medicines.

Knowledge of your past medical history is also very important in helping the physician choose the medicine most appropriate for you. The presence of other medical conditions will dictate if a particular medicine can or cannot be given. Because some allergic reactions to medicines can cause death, it is especially important for the physician to know about any allergies you have to specific medicines.



Some prescription medicines, particularly narcotics, may be used as drugs of abuse. People with a history of a substance abuse problem are particularly prone to relapse when using these medicines for medical purposes. Also, many over-the-counter elixirs and syrups used in the treatment of cold symptoms contain alcohol and their use may be a factor in relapse. If you have a history of substance abuse problems or alcoholism, it is very important that you give your physician this information.

Your pharmacist's role



Your pharmacist is trained to help you use prescription and over-the-counter medicines most effectively. To assist the pharmacist in helping you in the best possible manner, the pharmacist also needs information on the medicines you are taking.

You should use the same pharmacy chain regularly.

This allows the pharmacist to maintain a complete and accurate history about any medicines you are taking. Each time your pharmacist fills a prescription, your prescription profile, or list of medicines used, is updated, thereby providing current information as well.

Sometimes you may have difficulty remembering all of the medicines you are taking and therefore will not be able to tell your physician this information. Your physician may unknowingly prescribe a medicine that should not be taken along with other medicines you already take. When you ask your regular pharmacist to fill the new prescription, then he or she can compare the new prescription to the list of other prescription medicines you have filled. This allows the pharmacist to discover when it would not be safe for you to take the new medicine. The pharmacist can alert both you and your physician. Your physician can then prescribe another medicine that is better suited for you.

Your pharmacist can assist you in many other ways. He or she can counsel you about how to take a prescription medicine so that the medicine will be the most beneficial. Your pharmacist can also counsel you about the appropriateness and safety of over-the-counter medicines such as cold or flu remedies, which you may want to use along with other medicines you regularly use.

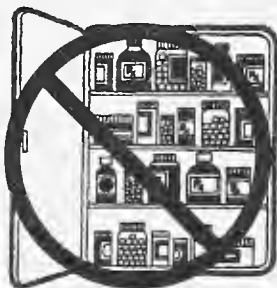
Storage of prescription medicines

You should store prescription and over-the-counter medicines in a way that will protect the medicine as well as members of the household. Some prescription medicines such as insulin and suppositories must be kept refrigerated but not frozen. Most others should be kept in cool, dry areas. The bathroom medicine cabinet is the most common location for storing medicines. Because this location is usually warm and humid, the bathroom medicine cabinet is an unsuitable location for protecting medicine. Another common location for storing medicines is a kitchen windowsill. This is also a bad location because medicines stored on a windowsill are often exposed to heat from sunshine through the window. Humidity and heat may cause a chemical alteration of the medicine. This alteration could cause the medicine to be ineffective or even harmful.

More appropriate locations for storing medicines include a bedroom drawer, a closet shelf or in a kitchen cabinet away from heat and moisture. Because some prescription medicines, particularly narcotics, may be used as drugs of abuse, you should be careful to store these medicines so that family members or others who may visit your home and who have a substance abuse problem cannot easily get them. Always be sure that medicines are stored where children cannot reach them. Ask your pharmacist how your medicines should be stored.

Over long periods of time, medicines naturally begin to alter their chemistry. This is why pharmacists are required by law to discard any medicines over a certain age rather than give them to a patient. Like a pharmacist, you should appropriately discard any old medicines. A general rule of thumb is that a medication is probably out-of-date or ineffective one year from when it was dispensed. Ask your pharmacist if your medicine is too old and should be discarded and the best way to dispose of old medicines. Some pharmacists will discard old medicines for you. Ask your pharmacist if he or she will help you discard your old medicines.

A pharmacist will not dispense medicines that have been returned by one patient to another patient. The pharmacist cannot guarantee that a returned medicine is of the same quality and condition as the medicine on his or her pharmacy shelf; someone may have improperly stored or even tampered with the returned medicine. Because returned medicines cannot be re-sold, the pharmacist is not able to refund money for unused medicines even if the medicine is not very old.



Taking medicines as prescribed

Prescription medicines are most effective when taken under certain conditions. The appropriate conditions may vary depending on the medicine. If you do not take the medicine as instructed, the medicine could be ineffective or you could experience unpleasant side effects. While taking some medicines you should avoid certain activities. Performing activities while taking some medicines that impair your ability, could result in harm to you or others.

Some prescriptions, such as those for infections, require you to take all of the medicine even though you will often feel better before you complete your prescription. You may feel you no longer need the medicine, but you should continue to take your medicine unless your physician tells you otherwise. Failure to take your medicine as prescribed by your physician could cause your symptoms to reappear.

Other prescriptions such as those for pain, will instruct

you to take the medicine only when you feel you need it and you will often have medicines 'left over'. You may not want to have medicine left over, particularly, if you live in a household where someone may have a substance abuse problem and would want to take your medicine if it were available. To prevent this, ask your physician to write a prescription directing the pharmacist to dispense a smaller amount of the medicine. You may also ask your physician to allow a limited number of refills in the event you need more medicine.

Both your physician and your pharmacist should tell you exactly how to take your medicine. Ask your physician and pharmacist to clarify any points that are unclear to you, including potential side effects. Never hesitate to contact your physician or pharmacist about any conditions that arise and that you feel may be related to the prescription medicine.

Medicines prescribed for others

You may occasionally think about taking medicines that were originally prescribed for other people. This is a very dangerous practice and something you should *not* do for several reasons! First, you have no guarantee about the conditions under which the medicines have been stored; recall that storage conditions affect the quality of the medicine. Secondly, taking a medicine that was not prescribed for you could be ineffective or even harmful.

Symptoms are an indication of a medical problem. Two patients' symptoms may sound similar. However, that does not mean that both patients have the same medical problem. For example, chest pain in one individual may be associated with a stomach problem whereas chest pain for someone else may indicate a heart problem. Medicines used to treat heart problems are not the same ones used to treat stomach problems. Someone else's medicine may not treat your specific problem.

There are many risks associated with taking medicines prescribed for someone else. Two or more medicines may react with each other and reduce their effectiveness or even cause them to be harmful. Your physician is aware of the potential for drug reactions and prescribes medicines that will not react with other medicines you are already taking.

Other medical conditions that you have also influence the physician's selection of medicine. Some medicines might be harmful if you have certain conditions. When prescribing a medicine, your physician considers other medical conditions and chooses medicines that will be safe for you.

You may not know how a medicine will react with one you are already using. Also, you may not know if it is safe to take a particular medicine when you have certain other medical conditions. Therefore, you are taking a dangerous chance if you choose to take someone else's medicine.

A Team Effort

When you receive a prescription, ask your physician to explain why you need the medicine and discuss the possibility of treatments that do not require you to take medicine. Ask your physician to explain how you should take the medicine. When you have your prescription filled, ask your pharmacist to explain how the medicine should be stored. Your pharmacist should also explain how the medicine needs to be taken so that it will be safe and effective. When you have questions or concerns about your medicines, do not hesitate to contact

your physician or pharmacist for answers. The safe and effective use of prescription medicines is a team effort between your physician, your pharmacist and you! □



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Editor's Note

The Prescription Drug Abuse, Misuse and Diversion Research Project is being conducted by The Governor's Institute on Alcohol and Substance Abuse, Inc. and the University of North Carolina at Chapel Hill School of Pharmacy with funding from the Substance Abuse Services Branch of the North Carolina Department of Health and Human Services.

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Successful Laparoscopic Management of Perforated Gallbladder Associated with *Salmonella javiana* Infection

John G. Lee, M.D., Michael E. McLeod, M.D., William C. Meyers, M.D., John Arthur, M.D., and G. Ralph Corey, M.D.

Our Patient

Cholecystitis is reported in up to 3% of patients with typhoid fever,¹ but it is uncommon in patients with salmonellosis due to species other than *S. typhosa*. We recently cared for a patient with *Salmonella javiana* cholecystitis complicated by perforation, which was successfully treated by laparoscopic cholecystectomy.

A 35-year-old man with history of biliary pain was admitted to another hospital for evaluation of profuse, watery diarrhea, right upper quadrant (RUQ) abdominal pain, myalgia, and fever. Symptoms had progressed over a 24-hour period. Physical examination showed a febrile, ill-appearing man with RUQ pain but no rebound tenderness. Complete blood count, liver function tests, and stool wet mount examination were normal. An abdominal ultrasound revealed a solitary gallstone without suggestions of cholecystitis. A computed tomographic (CT) scan of the abdomen was unremarkable. A radionuclide scan failed to visualize the gallbladder. The possibility of cholecystitis or perforated viscus was entertained, but a stool culture

taken on admission grew *Salmonella javiana* and a diagnosis of salmonella enteritis was made. The patient was given an appropriate broad-spectrum antibiotic and was transferred to Duke University Medical Center for further evaluation when he failed to improve after two days of therapy.

On arrival he was in moderate distress with a blood pressure of 96/80, pulse of 112 beats/minute, respiration of 32, and an oral temperature of 38.1° C. There was an ill-defined tender mass in the RUQ of the abdomen but no signs of an acute abdomen. There was a mild elevation of liver function tests, thought to be possibly due to sepsis. Cholecystitis was thought to be unlikely because of the absence of peritoneal signs and leukocytosis, and because of the unimpressive gallbladder ultrasound and normal CT scan. Cefazidime and clindamycin were administered for presumed salmonella enteritis.

Because of persistent RUQ pain and fever, CT scan of the abdomen was repeated on the fifth hospital day. It showed a 5.8 x 2.5 cm abscess anterior to the gallbladder. The peritoneal cavity was visualized by laparoscope, and a perforated gallbladder and surrounding abscess cavity was debrided through the laparoscope. All intraoperative cultures were negative. The patient's fever and

diarrhea resolved within the next six days and he was discharged home in good condition on the sixth post-operative day. He remains in good health six months after surgery.

Discussion

In approximately 70% of patients, salmonella infection causes a self-limited enteritis with watery diarrhea, nausea, fever, and crampy abdominal pain that resolves in two to five days without antibiotic therapy. Antibiotic therapy may hasten recovery, and is therefore recommended, only in immunosuppressed hosts or those with bacteremia or unremitting clinical course.

Failure to improve despite appropriate therapy should suggest a localized salmonella infection such as cholecystitis or abscess. A recent review identified only 10 published cases of culture-proven salmonella cholecystitis during the antibiotic era.² Seven of the 10 patients had gallstone disease (five had cholelithiasis, one, choledocholithiasis; and one, intrahepatic stone). The other three had acalculous cholecystitis. No gallbladder perforation was reported from this group.² In our patient, *Salmonella javiana* was not proven as the etiologic agent for cholecystitis because only the stool culture

From the Department of Medicine and Surgery, Box 3913, Duke University Medical Center, Durham 27710.

grew this bacterium. However, it was the only pathogenic organism isolated during this illness. We theorize that eight days of broad spectrum antibiotic therapy had sterilized the gallbladder.

Of 42,035 human isolates of *Salmonella* reported to the Center for Disease Control in 1986, only 416 were *javiana*.³ Clinical manifestations of infection with this organism include gastroenteritis, enteric fever, and localized infections.^{4,5} However, to our knowledge neither cholecystitis nor perforation of the gallbladder have been reported in association with *S. javiana*.

Perforation of the gallbladder occurs in 2% to 14% of patients with cholecystitis.^{6,8} The pre-operative diagnosis of perforation is difficult to make because the clinical presentation is similar to cholecystitis: fever, RUQ abdominal pain, nausea, and vomiting. Laboratory tests do not reliably differentiate between the two diseases.⁹ The treatment for salmonella cholecystitis and perforation is surgical removal and drainage. As our case illustrates, a laparoscopic approach with careful attention to debridement and irrigation can be successful and is less traumatic to an already very ill patient.

To emphasize the lessons we learned from this case: severe diarrhea may overshadow the symptoms of salmonella cholecystitis (fever, RUQ pain, and non-visualization of the gallbladder on radionuclide scanning). Nevertheless, a localized infection should be considered in all cases of salmonellosis that fail to improve despite appropriate antibiotic therapy or in cases with unexplained extraintestinal symptoms. Early surgical intervention using relatively less complicated techniques such as laparoscopic cholecystectomy may improve morbidity and mortality. □

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The Medicare Program

Exploring Federal Health Care Policy

Edward H. Kincaid, M.S. III

The medical care system is an albatross. It has evolved into a financial and political nightmare for our government and our citizens and consequently is now undergoing intense scrutiny. Its current problems are complex and highly interrelated, and are political, social, and economic in nature. Some of the more visible troubles of the health care system are:

- A large uninsured and underinsured population;
- An inflation rate for medical care that exceeds the Consumer Price Index (CPI);
- A technology explosion that creates economic and ethical ramifications;
- A near absence of competitive market forces because patients are insulated from costs of services;
- A focus on cure rather than prevention.

Not surprisingly, the public looks to the federal government for guidance with these problems. It is thus appropriate to examine the Medicare program, the largest form of government intervention in the medical marketplace, for clues as to how the government has responded to health-related problems. The history of the Medicare system, from its origin as a cost-based reimbursement system to the current Prospective Payment System, demonstrates the impact of federal policy on the health care system. The lessons learned from that history, combined with current social, financial, and political conditions allow us to assess whether the federal government has been a prudent payer for medical services.

The History of Medicare

Medicare finances health care for the elderly. Part A covers in-patient hospital, nursing home, and home health services; part

B covers out-patient hospital, physician, and limited ambulatory care services. Part A is financed by a payroll tax on employers and employees and provides coverage for individuals who are:

- 65 and over and who receive Social Security benefits or railroad retirement benefits;
- permanently and totally disabled for two years or more;
- victims of end-stage renal disease.

Enrollment in Part B is voluntary and is available to individuals with Part A coverage who pay a premium of \$28.60 per month (in 1991).¹ Part B is underfinanced by this premium and thus requires substantial and ever-increasing input of general revenues.

In 1965, President Lyndon Johnson made Medicare part of his "Great Society" theme. At that time many states made some provision for health care for the elderly and the poor, and states still retain responsibility for coverage for the poor under the Medicaid program. On July 30, 1967, Public Law 89-97 brought Medicare and Medicaid into existence. President Johnson signed the legislation in Independence, Missouri, home of Harry Truman, an outspoken proponent of national health insurance. Among other purposes, the law aimed to provide: a hospital insurance program for the aged under Social Security with a supplemental medical benefits program and an expanded program of medical assistance; increased benefits under the Old Age, Survivors, and Disability Insurance System; and an improved federal-state public assistance program.²

Nationalized health insurance was not a new idea in 1965. In 1912, presidential candidate Theodore Roosevelt made national health insurance part of his reelection platform. Proposals were regularly submitted to Congress thereafter, including a version by President Nixon in the early 1970s. These plans failed because of opposition by the American Medical Association, and because of questions about financing. Public Law 89-97 was seen as a stop-gap measure to be superseded by

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universal coverage in 1968 under a continued Democratic presidency of either Johnson or Hubert Humphrey. The election of Nixon made Medicare the fixture it is today.³

Medicare Today

Medicare expenditures have risen dramatically since 1967. Table 1 shows several trends that account for this. An aging population and the extension of Social Security coverage has increased the number of enrollees. Furthermore, there is an increase in expenditures beyond that due to inflation and increased numbers of enrollees. Since 1967 the average annual increase in expenditures per enrollee has been about 12%, as compared to 6% annual increase in CPI.⁴ There is a rising percentage of the federal budget spent on Medicare, as evidenced in the last column. These trends are likely to continue or even intensify as the number of elderly continues to rise.

Figure 1 shows that Medicare provided 17% of all medical services in this country. Further, 63% of Medicare dollars went to hospitals and only 38% to general health care. Hospitals receive an average of 49% of their revenues from the federal government,⁵ and as a result of such heavy reliance on the government, tinkering with the Medicare system greatly influences the viability and fiscal priorities of hospitals, as will be seen later.

During the deliberations preceding passage of Medicare in 1965, the fear that hospitals and physicians would boycott the system led to the stipulation of cost-based reimbursement.⁶ This system paid for direct costs, such as room and board, diagnostic tests, surgical costs, and supplies; overhead costs such as administration, utilities, rent, depreciation, interest expenses, and teaching costs (residents, nurses, students, etc.).⁶ The cost-based reimbursement system provided no incentive for the hospital to operate efficiently. The more that was spent, the more the hospital received from the government, a portion of which was profit. The reimbursement program was administered through Blue Cross and Blue Shield, keeping the govern-

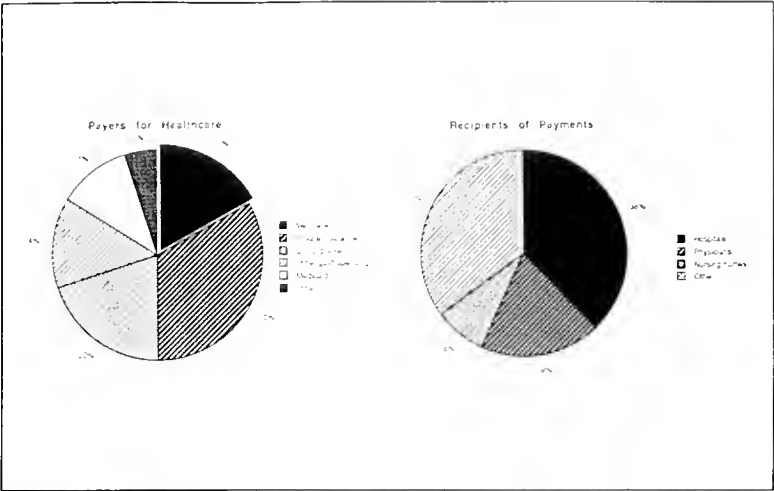


Figure 1: Payers and recipients of health care dollars. (Adapted from Levit et al¹)

ment from scrutinizing the services they were buying and incorporating another source of inefficiency.

Medicare hospital expenditures increased 18% per year from 1967 to 1970. Overall inflation was very high, but not nearly as high as hospital cost inflation. In 1971, President Nixon instituted a freeze on wages and prices throughout the entire economy, including health care. Nixon's Economic Stabilization Program (ESP) allowed a predetermined inflation rate that varied by industry. Hospital costs were allowed to increase by approximately 6% per year between 1970 and 1974, when hospital lobby pressure finally succeeded in having the ESP regulations lifted.⁶ Thereafter, hospital expenditures rose at an even greater rate than before.

In reaction to soaring hospital expenditures after ESP, the government enacted legislation that gave it greater scrutiny over the operations of the hospital industry. Professional Standards Review Organizations (PSROs) were created to monitor the activities of hospitals, primarily admissions protocols and rates, and standards of care. The members of PSROs were mostly physicians, raising questions about their ability to regulate their own profession. This new legislation did little to slow Medicare expenditures, but did affect future health policy in another way. Diagnosis-related groups (DRGs) were created by

PSROs to monitor length of stay and other standards of care. The creation of DRGs was a fundamental part of the Prospective Payment System established later.

When President Carter took office in 1977, hospital costs were increasing at an annual rate about 8% higher than the CPI. In an attempt to balance the budget, he proposed a hospital cost containment bill limiting increases in hospital payments to the inflation rate plus 3%. This bill

Table 1. Selected Medicare expenditure data^{1,4}

Year	Medicare enrollees (millions)	Medicare expenditures (\$ millions)	Expenditures per enrollee (\$)	Medicare as % of gov't. expenditure
1967	19.5	4.9	251	3.1
1970	20.5	7.2	351	3.7
1975	25.0	15.7	628	4.7
1980	28.5	36.4	1277	6.2
1985	31.1	70.4	2264	7.4
1990	34.2	108.9	3184	n.a.

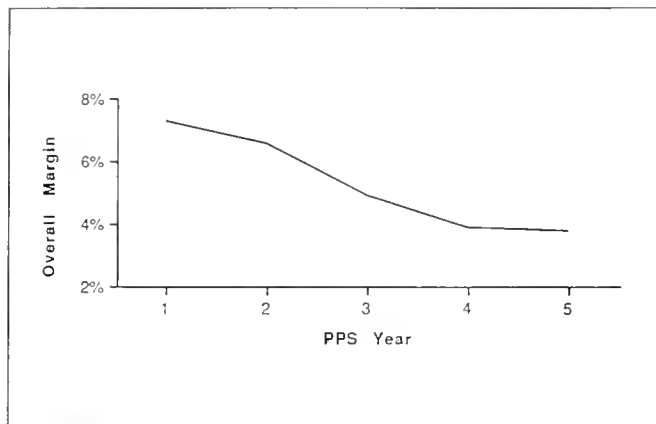


Figure 2: Hospital PPS margins, first five years of PPS. (Adapted from Guterman et al¹⁰)

was opposed vigorously by the hospital industry and the AMA, which countered by asking Congress to allow them to control costs internally. Congress agreed, and a coalition of hospitals, physician organizations, and insurance companies created the Voluntary Effort (VE). This did keep cost increases in line with overall inflation, which was already very high because of the oil shortages of the 1970s.

The voluntary cost containment success was short-lived, and after 18 months costs began increasing at their previous rates.⁶ The Carter Hospital Bill and the VE were important, however, because the highly charged battle opened the eyes of legislators to the nature of the health-care financing crisis. This fact and the large amounts of data on health costs generated during the late 1970s set the stage for future innovative solutions.

Cost Containment: New Approaches

The 1980s saw increasing conflict between the executive and legislative branches of government. Ronald Reagan did not make health care one of his early priorities, preferring to let market forces control the health-care industry. But after realizing the extent of medical cost inflation and its impact on the budget, his administration proposed cutting eligibility and benefits of Medicare. Congress opposed such a move and instead worked on cutting payments to providers. The Tax Equity and Fiscal Responsibility Act (TEFRA), implemented in 1982, established a limit on increases in Medicare payments. It used DRGs to classify patients into categories based on primary and secondary diagnosis, procedures performed, age, discharge status, and the presence of complications and comorbidities, and based payments to hospitals on an aggregate of these DRGs known as the case mix. Annual payment increases were limited to 1% over the "market basket," a cross-sectional representation of the goods and services purchased by hospitals and used by them to predict the costs of treating patients. Because of flaws in its design, TEFRA provided little,

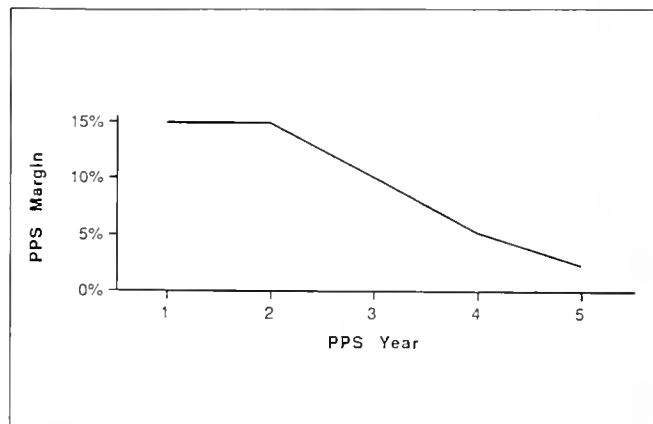


Figure 3: Hospital overall margins, first five years of PPS. (Adapted from Guterman et al¹⁰)

and largely ineffective, incentive for efficiency. Perhaps most importantly, TEFRA required the Secretary of the Department of Health and Human Services to develop a prospective payment system to be implemented in 1983.⁷ In essence, TEFRA was a bridge between retrospective and prospective reimbursement systems.

The Prospective Payment System

The Medicare Prospective Payment System (PPS) went into effect in October 1983. Hospitals were to be paid a prospectively determined rate for each patient based on the patient's DRG. This program was to be phased in over four years during which hospitals would be paid a blend of cost-based and prospectively-based payments.

Important provisions of the PPS included the following: 1) No payments were to be based on pre-PPS reimbursement rates; all hospitals started out equal except for a rural-urban differential. Prior to PPS, payments for certain procedures could vary as much as ten-fold (a hip-replacement could cost \$950 at one hospital and \$9,500 at another); these distinctions were eradicated. The rural-urban differential was based on the presumably lower labor costs in rural areas. 2) Payment rates for each DRG were to increase at the "market basket plus 1%" rate established under TEFRA. 3) Certain expenses, such as rent, depreciation, and medical education were to be reimbursed at cost. 4) Each state was required to establish a professional review organization (PRO), similar to the PSRO, to help regulate hospital quality.

It was intended that PPS would increase hospital efficiency by creating a system of rewards and punishments, since any discrepancy between DRG payment and actual cost would either be paid by the hospital or retained as added profit. In addition PPS sought to limit increases in the Medicare budget.

The effects of PPS have been, and will continue to be, intensely scrutinized. Perhaps the greatest fear was that PPS would decrease the quality of care Medicare patients received by encouraging premature discharges, lessened use of expen-

sive but beneficial technology, and fewer consultations. Fortunately, most studies show no decline in quality of care.⁸ Another fear was that hospitals would "upcode" DRGs in order to place a patient in a higher paying group. Studies do show a trend toward increasing severity in overall DRG submissions, but it is unclear whether this increase is due to "DRG creep" or actual case-mix change (that is, only sicker patients are admitted).⁹

One totally unexpected result of PPS was that hospital profitability rose substantially during the first few years. Figure 2, opposite, shows an average PPS margin—the percentage of PPS payments left after operating costs are deducted—of 15%. On reviewing these numbers, the federal government decided its initial DRG ranges were excessive and began ratcheting the rates down, abandoning the original "market plus one" annual increases. Figure 2 shows the rapid subsequent decline in PPS margins.

Cost Shifting

The decline in PPS margin led to the practice of cost shifting. While Figure 2 shows a rapid decrease in hospital "profits" from Medicare patients, there was a much slower decline in aggregate margin (Figure 3, opposite). Hospitals made up for Medicare losses by charging other payers increased rates. The bearers of these shifted costs were private insurers who, in turn, passed the costs on to businesses and individuals. Guterman and Califano estimate that every hospital bill and the average annual premium for business-sponsored health insurance is increased by 25% due to cost shifting.^{11,12}

Figure 3 does suggest a decreasing ability for hospitals to shift costs since their aggregate margin is declining. Many factors contribute to this decreasing ability, including greater enrollment in prepaid plans such as HMOs and PPOs, specific contracts between hospitals and large corporations, and greater use of prospective payment by private insurers. As a result, hospital closings almost doubled during the first four years of PPS versus 1980 to 1983 (Table 2), and access to care has become a problem in some rural and central urban areas.¹³

Because DRG rates for subsequent years are made only one year at a time, PPS creates a planning nightmare for hospital administrators who are unsure about future rates. This off-the-cuff rate setting is the result of political pressures on Congress to respond to budget deficits and to please constituents.

Table 2. Hospital closings before and after prospective payment⁵

	Number of hospitals closed		
	Urban Hospitals	Rural Hospitals	Total
1980-83	73	47	120
1984-87	128	116	244

Has PPS Controlled Cost?

On statistical grounds the PPS has saved money for the government. Medicare expenditures per enrollee have increased at an annual rate of approximately 7% since PPS compared to the previous 13%. Looking at the broader picture, however, it is important to realize that PPS has been subsidized by shifting costs for Medicare patients to individuals and private insurers. Hospital payments, the major portion of total Part A payments, have been controlled, but Part B payments have not. Since 1980, Part B expenditures per enrollee have increased at 20% per year and out-patient services by almost 33% per year¹⁴ because hospitals and physicians have increased billing for cost-reimbursed services under Part B. The government is now instituting a new payment system for physicians—the Resource-Based Relative Value System—in an attempt to control payments and to reimburse primary and secondary care physicians more equitably. The government will also attempt to control the amount of out-patient services billed by hospitals. The future will tell whether these policies succeed.

Is the Government a Prudent Payer?

Let us return to the question posed at the beginning of the paper: Has the government been a prudent payer for medical services? There are several criteria for assessing prudence: cost control, promotion of high-quality care, administrative efficiency, and positive effect on providers. Earlier we addressed the government's (in)ability to control the costs of Medicare. The Prospective Payment System has slowed Part A spending, but Part B spending has increased dramatically. There are two reasons for these cost increases: rise in the cost of medical care itself and increased utilization of services by consumers. These two variables have an inverse relationship (Figure 4) so that as inflation is controlled, utilization increases and, conversely, as utilization is curbed, inflation increases. This inability to con-

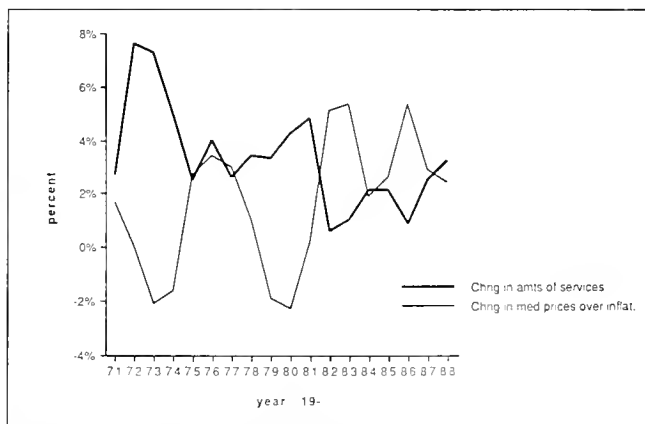


Figure 4: Changes in volume and price of medical care. (Adapted from The Robert Wood Johnson Foundation¹⁵)

Table 3. Administrative costs, 1990^{1,14}

Payer	Administrative cost as a % of total expenditure
Private Health Insurance	14.2
Medicaid	5.1
Medicare, Part A	3.6
Medicare, Part B	1.1
Medicare, total	2.6

trol costs is due to inefficiency throughout the system; no one party is to blame. Nevertheless, consumers probably should blame themselves more than they do. Levit et al report that 25% to 50% of health expenditure increases during the 1980s was due to increased utilization.¹ For example, between 1980 and 1990, the number of Medicare Part B claims per enrollee increased 143%, from 5.0 claims per enrollee per year, to 12.3.¹⁴ Consumers complain about high costs, but they demand more care. Even the government, the largest player in the reimbursement game, is not strong enough to counteract the systematic effects that increase health expenditures. It follows, therefore, that the government has failed to control its own costs. And so by this criterion the government has not been a prudent payer for health care.

Has the government been prudent in promoting high quality care for Medicare recipients? Some statistics may help: Kahn et al report a decreasing mortality rate for hospitalized Medicare patients since PPS was instituted.¹⁶ Between 1969 and 1986, life expectancy at age 65 increased almost two years (from 14.9 years to 16.7 years). In comparison, life expectancy at birth increased only four years (from 70.8 years to 74.8 years) during this time.⁴ In a recent survey, about two-thirds of Americans over 65 report good to excellent health.¹⁷ On the other hand, many critics point out that this country's relatively short life expectancy and high infant mortality compared to other industrialized nations indicates that we have spent our health care dollars poorly. We must remember, however, that our country is comprised of people of diverse origins, including immigrants from developing countries with historically poor health. This and the penchant of Americans for self abuse increase demand for health care and worsen our mortality statistics. It seems, therefore, that the elderly have received care they are satisfied with and are demanding more of, and which has increased their life expectancy. So in terms of quality of health care, the government is a prudent payer for health care.

The third part of the "prudent" question relates to administrative efficiency. Federal programs have traditionally been associated with administrative ineptitude. Ironically, the Medicare program spends the least on administration of all third party payers—2.6% of expenditures versus 14.2% for private insurers (Table 3). This discrepancy can be attributed, in part, to private insurers' costs for advertising, marketing, sales commissions, licensing fees, and taxes. In addition, the Medicare program, being much larger than any individual private insurer, benefits from economies of scale. For these reasons, Medicare is a cost-efficient payer, adding to the argument that the government is prudent.

One final aspect must be examined—the effect of government payment on providers. Perhaps the biggest problem with government-sponsored health care and with government programs in general is their dependence on the political process. I have shown earlier how legislators continually tinker with the Medicare program, hoping to simultaneously reduce expenditures and please their constituents. In the annual budget debates of Congress, questions of health take a back seat to questions about budget deficits. The interest on the national debt con-

sumes 14% of every tax dollar,⁴ and this large and ever-increasing expenditure cripples the ability of the government to effectively solve the health care crisis. The annual struggle to limit the deficit imposes strain on health

"Perhaps the biggest problem with government-sponsored health care and with government programs in general is their dependence on the political process."

care providers. Reimbursement rates change yearly, so providers, especially hospitals, find themselves in a constant state of uncertainty, unable to establish long-range policies. This lack of policy ultimately affects the cost and quality of care. By this fourth criterion of prudence, the government fails.

Overall, is the government a prudent payer? Only if "two out of four ain't bad." The government could increase its score easily in one way—by giving hospitals longer guarantees of reimbursement rates. But there is another question: What payer has done better? Of course, the answer is none. All payers have major problems, albeit different from those of the federal government. On a comparative basis, the government is no less prudent than other payers.

Overall, Medicare has shown that government-sponsored health care is feasible, but at times unwieldy. The positive features of Medicare include prospective payment (the only way ultimately to control costs), administrative efficiency, high quality of care, and service for a population that in the past has been vulnerable to the cold winds of catastrophic illness. On the other hand, Medicare has not been effective in controlling costs, and it has created something of a nightmare for providers.

Surprisingly, Medicare has gone from vigorous opposition by the AMA to one of general acceptance by physicians, and by society as a whole. The question now is not whether we should have government-sponsored health care for the elderly, but rather what form that care should take. That is a remarkable change in society's attitude towards government in health care. □

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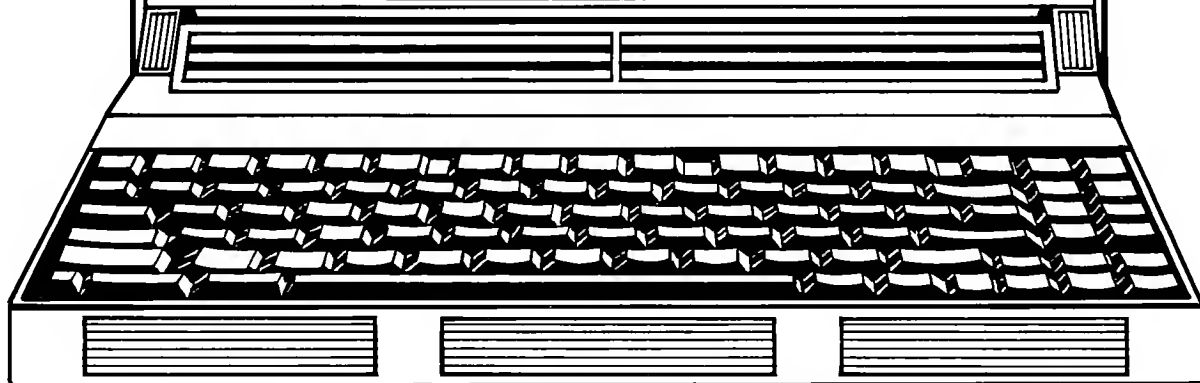
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Wilburt Cornell Davison, M.D.

One Hundredth Anniversary: 1892 - 1992

Jay M. Arena, M.D.

It is difficult to express in words my relationship with Dr. Wilburt Cornell Davison, who has meant so much to me and many others. As one of Duke University's first graduates and house officers, and as a long-time member of the pediatric faculty, I submit this brief commentary from a 42-year happy and rewarding association with Dr. Davison in all of these areas. Perhaps an historical account, never before published, will best illustrate how we all felt about this rumpel, unpretentious, witty, unique man—The Dean, as he was known—who was totally and unequivocally dedicated to Duke's School of Medicine.

This tale deals with the eight editions of his book, *The Compleat Pediatrician* (Figure 1), which he started at Johns Hopkins in Baltimore as a notebook of easily forgotten facts and treatment methods after his return from World War I in 1919. Although he used the Duke University Press name as publisher (with permission), he had the publication printed at a local printer (Seeman's), so that he could exercise full control of each book and its profits. Mead-Johnson Laboratories, which maintained a national listing of pediatricians, distributed card fliers free of charge publicizing the availability of a recent edition. Each member of the

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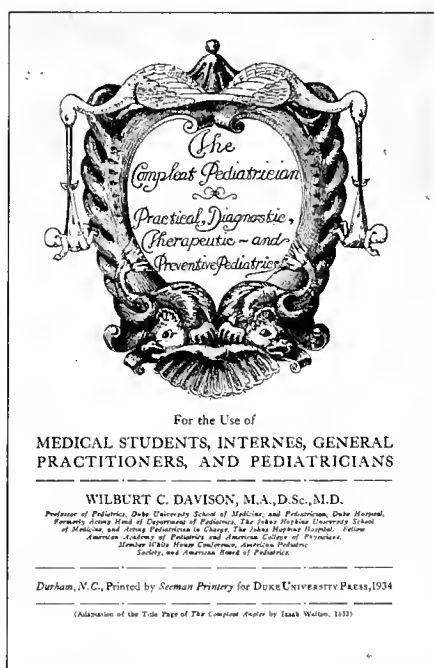


Figure 1: Frontispiece from *The Compleat Pediatrician*, by Dr. Davison, published in 1934 by Seeman Printery for the Duke University Press.

small house staff and faculty participated in the publication and received generous honorariums. With each edition, typographical errors or corrections were noted either verbally or by mail; the individual who discovered them was reimbursed 10 cents for each mistake that was reported.

Because of Dr. Davison's ingenuity, *The Compleat Pediatrician* was published and circulated at very low cost.

The final edition (the 8th—1961) cost \$4.50 by check or \$4.75 by credit card, and had a money-back guarantee. The sale of eight editions over the years accrued a net profit of nearly \$100,000. This money, placed in a separate account, was used as an emergency loan fund for needy students, house officers, faculty, and hospital personnel. No notes were signed, only an undated memo was made of the transaction. If and when the loan was repaid (most were outright gifts), the money was returned to the fund. A personal example occurred with our first-born, a daughter, when I had just finished my residency. My wife Polly had the usual 10 hospital-day, post-delivery of the times, and the hospital charge was \$95. As a proud first-time father, I had saved enough to take care of this "bill," but when I went to the business office to settle my account, Mrs. Campbell, the cashier, would not accept my payment, saying only that it had been taken care of. Of course, I knew who was responsible. I went immediately to Dr. Davison's office to repay him. His office was open, as usual (he had an open-door policy, so anyone could enter as long as no one else was in the office at the time). I walked in and we had a long conversation about what to do with the money that he would not accept. He suggested that I use it toward a down payment for a house in order to stop paying rent. He said he was willing to sign a note to assist us with this endeavor.



The author, left, and Dr. Davison at a Duke alumni event about 40 years ago. Dr. Arena and Dr. John P. McGovern compiled a book of reminiscences about Dr. Davison that appear in *Davison of Duke* (Fulton, MO: The Ovid Bell Press, 1980).

Dr. Davison was a frugal individual. He began his tenure at Duke in 1927 on an annual salary of \$12,000, and he kept it at that figure for 13 years before he allowed himself a raise, yet being generous to a fault for those with legitimate needs. He even helped pay for a home for his favorite orderly, Carl Rogers, whom he always referred to as his "assistant dean."

As a final note on the hundredth anniversary of Dr. Davison's birth, the following anecdote that I related during his memorial service on November 17, 1972, seems appropriate:

In the fall of 1955—Friday, October 14, to be precise—a private plane from Ross Laboratories of Columbus, Ohio, dropped down from a rain-laden sky to

pick up Dr. Davison and some members of his pediatric staff, myself included, to attend the Duke-Ohio State football game the following day. Incidentally, Duke won 20-14 in spite of being overwhelming underdogs and in spite of Ohio State's All Americans Cassidy and Parker. (But Duke had a quarterback by the name of Sonny Jurgensen who later went on to become a driving force for the Washington Redskins.)

The flight to Columbus was a rough and stormy trip, and, believe it or not, the topic of death was bantered about. Dr. Davison suddenly turned to me and said, "Arena, you don't need to fear death; you and the Pope are such good friends. Surely you'll go straight to heaven. As for me,"

he continued, "if there is such a place, I will never make it."

A passage from the Bible flashed through my mind, which I recounted—a slightly altered version, perhaps my own to be sure:

"...Then the King will say to those on his right hand, 'Come, you whom my Father has blessed, take for your heritage the kingdom prepared for you since the foundation of the world. For I was hungry and you gave me food; I was thirsty and you gave me drink; I was a stranger and you made me welcome; I was naked and you clothed me; I was sick and you visited me; I was in prison and you came to see me.'

Then the virtuous will say in reply, 'Lord, when did we see you hungry and feed you; or thirsty and give you drink? When did we see you a stranger and make you welcome; when did we see you naked and clothe you; or sick or in prison and go and visit you?' And the King will answer, 'I tell you solemnly, insofar as you did

this to one of the least of these brothers of mine, you did it to me.'"

Turning to Dr. Davison I said, "You have done all of these things many, many times, and your chances of getting to heaven are better than mine."

I knew he was pleased with this passage and with my reply, for after a long pause he said, in an uncharacteristically subdued voice, "Maybe I'll make it after all."

Those of us who had known The Dean all those years—former students, house officers, colleagues, and warm devoted friends—knew that he would make it. And one hundred years after his birth and 20 years after his death, we still believe he made it. □



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Why Do Practitioners Contribute To the Medical Literature?

A Survey of Doctors' Writing Habits

Divyang Joshi

Editor's Note: Mr. Joshi is a senior at the University of California at Los Angeles and is in the process of applying to medical schools. He conducted a survey and wrote a paper about doctors' writing habits as part of a course entitled "Advanced Exposition for Science and Technology." His professor suggested that he submit it to one of the journals he referenced. He sent it to the *North Carolina Medical Journal* because he found Dr. John M. Falletta's article "Physicians as Science Writers" (NC Med J 1987;48:41-3) a helpful resource. We hope you find Mr. Joshi's observations as interesting as we did.

During the past one hundred years, the authorship of medical articles has changed considerably. At the turn of the century, most medical papers were written by practicing physicians who followed the Hippocratic tradition¹ to pass on their knowledge by "precept, lecture, and every other mode of instruction." Furthermore, there were no full-time researchers in any of the branches of medicine.² However, as the 20th century has advanced, the practicing physician has slowly lost ground to the researcher as author, and these days medical writing is usually authored by a researcher. Practitioners still do contribute to medical literature although the number and impact of their contributions seem less than they were a century ago.²

Medical researchers spend a large portion of their time applying for grants and attempting to publish articles, research papers, etc. For them, "publish or perish" is a way of life. Private practitioners, on the other hand, are not known for their writing (except medical histories and prescriptions). Nonetheless, according to Hagan,³ practitioners can contribute significantly to the field of medicine because they perform more surgeries, handle more patients, and provide more continuous patient care than research doctors do. A physician's writing ability can be an important factor in expanding medical knowledge and in relating the knowledge gained through direct contact with patients. The very act of writing, Huth explains,¹ forces doctors to study their observations in detail and to coherently and sequentially structure them. The process of writing thereby clarifies the doctor's thoughts by enhancing his or her ability to communicate findings and their implications to others.

The medical field has already begun to recognize the need for skill in communication through writing. The new Medical College Admission Test (MCAT) includes a mandatory essay section to help medical schools decide whether or not an applicant is able to communicate clearly. Tattersall,⁴ a private practitioner, points out the need for practitioners' contributions by relating the story of his own shoulder problem that many textbooks dismissed as simply a condition of old age. Without the input of practicing physicians cases like his would lead to incorrect diagnoses and treatments and, possibly, to malpractice lawsuits. Tattersall also notes that doctors who write well can enhance the doctor-patient relationship by providing to patients, who often are unable to recall the doctor's verbal communications, a written document of their condition and the doctor's orders. Such personalized and specific documents have much greater instructional value than a general pamphlet.

Many of the thousands of biomedical journals published throughout the world solicit contributions by medical practitioners and give detailed instructions on exactly how an article should be constructed.^{5,6} In addition, the American Medical Association's *Manual of Style* offers guidelines on writing for the medical field. Newspapers and other journalistic media ask doctors to contribute their knowledge so that the public may be better informed about medical issues.⁷

In the face of these facts, I became curious as to just how many practice-based doctors actually do contribute to the medical literature. This report examines the question of whether or not practice-based doctors write and why. I found that a little

more than one-quarter of the doctors I surveyed did write, mainly for educational purposes; the others said that lack of time and interest were the main reasons that they did no "extracurricular" writing.

Survey Methods

I contacted doctors affiliated with an HMO who practice at two hospitals, one in San Jose, California, and one in Los Angeles, California. I sent questionnaires to a sample of practicing doctors in several different medical fields (e.g., pediatrics, gynecology, internal medicine, etc). Research-based doctors were excluded because I assumed they were already heavily engaged in writing.

I designed a one-page questionnaire (Figure 1) that took 30 seconds or less to complete. The questionnaire had five multiple choice and yes/no questions with a fill-in section for those choices not provided. The first two questions established the respondent's field of practice and whether or not this included

surgery. The third question established whether or not the doctors wrote outside the requirements of their office. A "yes" response to Question 3 led to questions about the type of writing, the frequency of this writing, how often they co-authored a paper, and their motivation for writing. Doctors answering "no" to Question 3 were asked to supply the reason(s) they did not write. More than one response was permitted for some questions. A brief explanation of the purpose of the survey and directions for completing the form preceded the questions. The questionnaire ended with a statement of thanks to the doctors and information on how to obtain a copy of the final report.

The questionnaires were delivered by hand (in Los Angeles) or by mail (in San Jose) to a hospital administrator who was asked to distribute them at the beginning of a general meeting attended by the hospital's doctors. After two weeks, the surveys were collected by hand (Los Angeles) and by mail (San Jose), and the results were analyzed.

Survey Results

A total of 76 doctors completed the questionnaire. Of these, 21 (28%) responded that they engaged in medical writing outside the requirements of their practice while the remaining 55 (72%) did not. Twenty of the 21 doctors said they wrote one or two papers a year while one doctor claimed three to five publications per year. Of the 21 doctors who did write, 38% wrote journal articles; 33% wrote research papers; 33% wrote for pleasure; 29% wrote medical pamphlets; 14%, newspaper or magazine articles; 14% prepared lectures; and 5% wrote books. Most of the doctors wrote for educational purposes: 67% to advance knowledge in their field; 43% to inform or educate the public; and 33% to prepare for lectures. Seven of the 21 (33%) said they wrote to gain an elevated standing in their field.

Of the 55 doctors who did not write, 56% said they had no interest in writing; 47% cited lack of time; 15% cited lack of writing experience as the reasons for not contributing to the medical literature; and 5% said they did not write because there was no substantive reward for writing.

A total of 27 surgeons completed the questionnaire; 22% did write outside the office compared to 30% of the 49

Figure 1: Survey Questionnaire

1. Please circle the field of medicine in which you hold your practice:

a. Cardiology	g. Nuclear Medicine	m. Physical Therapy
b. Dermatology	h. Obstetrics	n. Plastic Surgery
c. Ear-Nose-Throat	i. Ophthalmology	o. Radiology
d. Gynecology	j. Optometry	p. Urology
e. Internal Medicine	k. Orthopedics	r. Other _____
f. Neurology	l. Pediatrics	
2. Do you perform surgery? Yes No
3. Other than medical histories and prescriptions do you engage in any other type of writing? Yes No
4. a) If yes, please circle one of the following:

a. research paper	e. authoring a book
b. medical pamphlets	f. just for pleasure
c. journal articles	g. other _____
d. magazine/newspaper articles	

 b) Do you co-author papers? Always Sometimes Never
- c) Approximately how many written works do you publish per year?

a. 1-2	d. 7-9
b. 3-5	e. 10 or more
c. 5-7	
- d) What is your motivation for writing?

a. inform the public
b. furthering knowledge in your field
c. gain elevated standing
d. other _____
5. If you answered "no" to question 3, what is stopping you?

a. not enough time	d. lack of writing experience
b. no interest	e. other _____
c. lack of substantial rewards	

non-surgical practitioners. Furthermore, when analyzed by geographical areas studied, 36% of the 55 respondents from Los Angeles wrote compared to only 5% of the 21 respondents from San Jose.

Discussion

It is interesting that the percentage of surgeons who wrote corresponded closely with that of the non-surgical doctors. I had expected that a lower percentage of surgeons would write because of the long hours and stressful nature of their job. It is possible that surgeons, being able to examine the interior of the body, may come across new or clarifying phenomena not detectable from the external signs to which most other doctors are limited. For this reason, surgeons may have more impetus to write than would otherwise be expected. Or it may be that the stimulus to write arises from impulses totally divorced from practice itself.

The trends exhibited by San Jose and Los Angeles doctors are intriguing. Only 5% of San Jose respondents, compared to 36% of Los Angeles respondents, indicated that they engaged in extracurricular writing. Since fewer questionnaires were returned by San Jose doctors, the class of San Jose doctors who do write may be underrepresented, but it is more likely that the results stem from other considerations. Perhaps the greater density and diversity of the population exposes Los Angeles doctors to a greater number of patients and medical phenomena, and thus provides them with more opportunity and reason to write. Or possibly those doctors who are moved to record their observations and thoughts are drawn to Los Angeles while doctors who do not have such leanings gravitate to San Jose. In any case, further exploration will be needed to confirm whether doctors from the two areas do indeed differ and, if so, the reasons for this difference.

A number of studies support and explore in further detail my findings regarding the reasons doctors do or do not write. Huth¹ and Palmer⁶ both found that fear of rejection keeps doctors from submitting to journals. According to Huth, doctors (like everyone else for that matter) have a small chance that

their article will be accepted by the first journal that sees it, but eventually, with enough persistence, some journal will usually accept it. However, this long and hard road, often including a processing fee (approximately \$50) for submissions and lacking any monetary reimbursement,^{2,8} seems to discourage doctors from even attempting to submit anything. (Recall that 26 doctors in my survey said that they had "no time" for extracurricular writing.)

Even though the acceptance rate of articles is low, doctors still have advantages that should lessen the fear of rejection. First, it should be noted that some journal articles concerning medicine (including the one you are reading) are authored by individuals who do not even hold an M.D. degree. Doctors should realize that they are more than qualified to submit an article. Second, potential contributors should take advantage of the step-by-step instructions on how to prepare and submit a paper provided by journals. Finally, doctors, who are uncomfortable with their writing skills and the "rigid structure of the scientific article as a pattern of communication,"⁷ may choose to have their work written by a specialist, as Falletta⁸ suggests. In this way, doctors may find more time for their work, including finding further information worth publishing, and the journal may get a more immediately publishable manuscript. However, cost and the individual doctor's preference for conveying his or her findings in a personal manner⁹ may diminish interest in using a writing specialist.

Studies by Fye² and by Yanoff and Burg¹⁰ indicate that medical school experience and present medical literature both contribute to the low percentage of doctors who write. These authors state that medical schools and medical literature do not prepare doctors even for everyday writing tasks such as medical histories and discharge summaries. Perhaps, as Bayard Holmes¹¹ hopes, "With an improved quality of medical education will soon appear another standard of medical practice and medical culture. The medical literature will improve in quality and quantity." Perhaps the change in format of the MCAT to include a written section is an indication that the medical schools may begin to teach students to write in a manner that allows them to be confident of what they have to offer the medical literature. □

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27103. 919/716-4450

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tion, Bowman Gray School of
Medicine, Winston-Salem
27103. 919/716-4450

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8165. 919/966-4032

November 19-22

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Info: Office of CME, DUMC,
Durham 27710. 919/684-6485

November 20

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Credit: 6.5 hours Category I, AMA
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Medicine, CB #7000, 231
MacNider Bldg., Chapel Hill
27599-7000. 919/962-2118

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 No time to eat or play
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—Kathleen Anne Dunn, M.D.

Dr. Dunn wrote this poem to sort out her emotions after helping to coordinate a major grant proposal involving three North Carolina universities. She works in the Division of Research, Department of Emergency Medicine, East Carolina University, School of Medicine, Greenville.

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FAMILY PHYSICIAN: to join busy solo doctor in suburban Raleigh, NC. Excellent working conditions, beautiful office, competitive compensation, good hospitals. Prefer recent FP residency graduate, but other primary care doctors considered. Please respond with CV or resumé to Office Manager, 605 Benson Road, Garner, NC 27529.

WANTED—GENERAL SURGEON—BC/BE: to join two-surgeon office, sharing partnership in Raleigh, NC. We have a new (2/92) 3,000-square-foot office in prosperous location. Third surgeon to start July 1993. Contact Drs. Quigless and Long at North Raleigh Surgical Associates, P.O. Box 20127, Raleigh, NC 27619. 919/571-1170.

BUSY GENERAL AND VASCULAR SURGEON: seeks general-vascular surgeon to associate. Located southern Piedmont North Carolina. 450-plus bed hospital. Send CV to Powell Surgery Clinic, 320-C Copperfield Blvd., Concord, NC 28025, or call 704/782-6978.

FREESTANDING CLINIC—URGENT CARE/OCCUPATIONAL MEDICINE: Immediate opening in the

Piedmont area of North Carolina for aggressive physician interested in long-term career commitment. Excellent salary, fringes, plus a progressive profit-sharing plan. Call or send CV to: Dr. Jeffrey A. Smith, 613 E. Roosevelt Blvd., Monroe, NC 28112. Phone 704/283-8193.

"HAPPINESS AND PROFESSIONAL SATISFACTION—Prevention of Physician Burnout": Two experienced physicians, a psychologist, and a financial advisor will facilitate at a coastal retreat. March 5-7, 1993, Seabrook Island, SC. CME credits. Room, meals, and tuition: \$185. Write Donald E. Saunders, Jr., M.D., USC School of Medicine, 3555 Harden St. Ext., Columbia, SC 29208, or call 803/253-4214.

MICROSCOPE WANTED: My son, a young would-be physician craves an inexpensive working microscope, any age or make. Please call 919/787-7307 (Raleigh) anytime.

SEEKING BC/BE PEDIATRICIAN: to replace retiring partner. Four-man group, Gastonia, NC. Call 704/867-6081 for details. Gastonia Pediatric Associates.

FOR SALE OR LEASE: in Charlotte, NC. Excellent practice in Pediatrics and young adult medicine. Office is in prime location. Fully equipped lab and six examining rooms. Contact 704/364-0324.

NORTH CAROLINA: Six-member internal medicine group seeks BC/BE internist, endocrinologist, or rheumatologist. Located in beautiful mountain community, 25 miles west of Asheville. Send CV to Dr. Linger, 102

Hospital Drive, Suite 1, Clyde, NC 28721, or call 704/452-0331.

N.C., BOONE: Experience the "High Country" of the Blue Ridge Mountains. University town, excellent public schools, unlimited outdoor activities. Congenial independent contractor group seeks BC/BP physician for 17,000/year ED. New ED facility. Excellent back-up. Competitive hourly salary plus liability. Contact Allen Brandon, M.D., Watauga Medical Center, P.O., Box 2600, NC 28607, or call 704/262-4165.

ASHEVILLE, NC: Lucrative internal medicine practice for sale by retiring physician who is willing to finance. May begin as a partner with guarantee. Debt-free new office with a \$300k to \$340k yearly income. Send CV or inquiries to Angeline Cadenhead, RN, 48 Independence Blvd., Asheville, NC 28805.

FOR SALE: EKG Terminal System 107A Comp-U Med. \$3,800 new, now \$1,600, plus accessory testing gear and supplies. Dr. David Dauphine, P.O. Box 467, Blowing Rock 28605. Phone 704/295-9896; Fax 704/295-9897.

AFFORDABLE ACTIVE SOLO FAMILY PRACTICE: Available due to planned retirement. Could expand to two-person group if desired. Same rented location since 1960. Loyal staff. New 230-bed (all private room) hospital. Call back-up and specialty coverage. Numa Carter, Jr., M.D., 512 W. Dixon Blvd., Shelby, NC 28152. 704/487-7540 (office); 704/482-1717 (home).

Aphorisms of the Month

"The Body and Mind"

Edited by Daniel Sexton, M.D.

As the strength of the body lies chiefly in being able to endure hardships, so also does that of the mind.

—John Locke

The most uninformed mind, with a healthy body, is happier than the wisest valetudinarian.

—Thomas Jefferson

The mind may undoubtedly affect the body; but the body also affects the mind. There is a reaction between them; and by lessening it on either side, you diminish the pain on both.

—Leigh Hunt

Minds, like bodies, will often fall into a pimply, ill-conditioned state from mere excess of comfort.

—Charles Dickens

Body and soul cannot be separated for purposes of treatment, for they are one and indivisible. Sick minds must be healed as well as sick bodies.

—C. Jeff Miller

Future generations, paying tribute to the medical advances of our time will say: "Strange that they never seemed to realize that the real causes of ill-health were to be found largely in the mind, and that even in 1965 there was hardly a teacher who could talk about sex except in biological terms" (which I must say takes most of the interest out of it).

—Sir Robert Platt

Send your favorite aphorisms (typed and double-spaced) to: Daniel Sexton, M.D., Box 3605, DUMC, Durham, NC 27710.

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†Constipation, which is easily managed in most patients, is the most commonly reported side effect of Calan SR.

‡Verapamil should be administered cautiously to patients with impaired renal function.

BRIEF SUMMARY

Contraindications: Severe LV dysfunction (see *Warnings*), hypotension (systolic pressure < 90 mm Hg) or cardiogenic shock, sick sinus syndrome (if no pacemaker is present), 2nd- or 3rd-degree AV block (if no pacemaker is present), atrial flutter/fibrillation with an accessory bypass tract (eg, WPW or LGL syndromes), hypersensitivity to verapamil.

Warnings: Verapamil should be avoided in patients with severe LV dysfunction (eg, ejection fraction < 30%) or moderate to severe symptoms of cardiac failure and in patients with any degree of ventricular dysfunction if they are receiving a beta-blocker. Control milder heart failure with optimum digitalization and/or diuretics before Calan SR is used. Verapamil may occasionally produce hypotension. Elevations of liver enzymes have been reported. Several cases have been demonstrated to be produced by verapamil. Periodic monitoring of liver function in patients on verapamil is prudent. Some patients with paroxysmal and/or chronic atrial flutter/fibrillation and an accessory AV pathway (eg, WPW or LGL syndromes) have developed an increased antegrade conduction across the accessory pathway bypassing the AV node, producing a very rapid ventricular response or ventricular fibrillation after receiving I.V. verapamil (or digitalis). Because of this risk, oral verapamil is contraindicated in such patients. AV block may occur (2nd- and 3rd-degree, 0.8%). Development of marked 1st-degree block or progression to 2nd- or 3rd-degree block requires reduction in dosage or, rarely, discontinuation and institution of appropriate therapy. Sinus bradycardia, 2nd-degree AV block, sinus arrest, pulmonary edema and/or severe hypotension were seen in some critically ill patients with hypertrophic cardiomyopathy who were treated with verapamil.

Precautions: Verapamil should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of overdosage. Verapamil may decrease neuromuscular transmission in patients with Duchenne's muscular dystrophy and may prolong recovery from the neuromuscular blocking agent vecuronium. It may be necessary to decrease verapamil dosage in patients with attenuated neuromuscular transmission. Combined therapy with beta-adrenergic blockers and verapamil may result in additive negative effects on heart rate, atrioventricular conduction and/or cardiac contractility; there have been reports of excessive bradycardia and AV block, including complete heart block. The risks of such combined therapy may outweigh the benefits. The combination should be used only with caution and close monitoring. Decreased metoprolol and propranolol clearance may occur when either drug is administered concomitantly with verapamil. A variable effect has been seen with combined use of atenolol. Chronic verapamil treatment can increase serum digoxin levels by 50% to 75% during the first week of therapy, which can result in digitalis toxicity. In patients with hepatic cirrhosis, verapamil may reduce total body clearance and extrarenal clearance of digitoxin. The digoxin dose should be reduced when verapamil is given, and the patient carefully monitored. Verapamil will usually have an additive effect in patients receiving blood-pressure-lowering agents.

References: 1. Data on file, Searle. 2. Edmonds D, Würth JP, Baumgart P, et al. Twenty-four-hour monitoring of blood pressure during calcium antagonist therapy. In: Fleckenstein A, Laragh SH, eds. *Hypertension—the Next Decade: Verapamil in Focus*. New York, NY: Churchill Livingstone; 1987:94-100. 3. Midtbo KA. Effects of long-term verapamil therapy on serum lipids and other metabolic parameters. *Am J Cardiol*. 1990;66:131-151. 4. Fagher B, Henningsen N, Hulthén L, et al. Antihypertensive and renal effects of enalapril and slow-release verapamil in essential hypertension. *Eur J Clin Pharmacol*. 1990;39(suppl 1):S41-S43. 5. Schmieder RE, Messerli FH, Garavaglia GE, et al. Cardiovascular effects of verapamil in patients with essential hypertension. *Circulation*. 1987;75:1030-1036. 6. Midtbo K, Lauve O, Hals O. No metabolic side effects of long-term treatment with verapamil in hypertension. *Angiology*. 1988;39:1025-1029.

Disopyramide should not be given within 48 hours before or 24 hours after verapamil administration. Concomitant use of flecainide and verapamil may have additive effects on myocardial contractility, AV conduction, and repolarization. Combined verapamil and quinidine therapy in patients with hypertrophic cardiomyopathy should be avoided, since significant hypotension may result. Concomitant use of lithium and verapamil may result in an increased sensitivity to lithium (neurotoxicity), with either no change or an increase in serum lithium levels; however, it may also result in a lowering of serum lithium levels. Patients receiving both drugs must be monitored carefully. Verapamil may increase carbamazepine concentrations during combined use. Rifampin may reduce verapamil bioavailability. Phenobarbital may increase verapamil clearance. Verapamil may increase serum levels of cyclosporin. Verapamil may inhibit the clearance and increase the plasma levels of theophylline. Concomitant use of inhalation anesthetics and calcium antagonists needs careful titration to avoid excessive cardiovascular depression. Verapamil may potentiate the activity of neuromuscular blocking agents (curare-like and depolarizing); dosage reduction may be required. There was no evidence of a carcinogenic potential of verapamil administered to rats for 2 years. A study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor, and delivery only if clearly needed. Verapamil is excreted in breast milk; therefore, nursing should be discontinued during verapamil use.

Adverse Reactions: Constipation (7.3%), dizziness (3.3%), nausea (2.7%), hypotension (2.5%), headache (2.2%), edema (1.9%), CHF, pulmonary edema (1.8%), fatigue (1.7%), dyspnea (1.4%), bradycardia: HR < 50/min (1.4%), AV block: total 1°:2°:3° (1.2%), 2° and 3° (0.8%), rash (1.2%), flushing (0.6%), elevated liver enzymes, reversible non-obstructive paralytic ileus. The following reactions, reported in 1.0% or less of patients, occurred under conditions where a causal relationship is uncertain: angina pectoris, atrioventricular dissociation, chest pain, claudication, myocardial infarction, palpitations, purpura (vasculitis), syncope, diarrhea, dry mouth, gastrointestinal distress, gingival hyperplasia, ecchymosis or bruising, cerebrovascular accident, confusion, equilibrium disorders, insomnia, muscle cramps, paresthesia, psychotic symptoms, shakiness, somnolence, arthralgia and rash, exanthema, hair loss, hyperkeratosis, macules, sweating, urticaria, Stevens-Johnson syndrome, erythema multiforme, blurred vision, gynecomastia, galactorrhea/hyperprolactinemia, increased urination, spotty menstruation, impotence.

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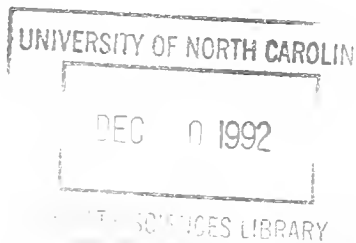
North Carolina Medical Journal

For Doctors and their Patients



Managing Pediatric Asthma in North Carolina

Rubin F. Maness, M.D.



Contents 618

Zantac[®] 150 Tablets
(ranitidine hydrochloride)
Zantac[®] 300 Tablets
(ranitidine hydrochloride)
Zantac[®] Syrup
(ranitidine hydrochloride)

CONDENSED
BRIEF SUMMARY

The following is a brief summary only. Before prescribing, see complete prescribing information in Zantac[®] product labeling.

INDICATIONS AND USAGE: Zantac[®] is indicated in:

1. Short-term treatment of **active duodenal ulcer**. Most patients heal within 4 weeks. Studies available to date have not assessed the safety of ranitidine in uncomplicated duodenal ulcer for periods of more than 8 weeks.
2. **Maintenance therapy** for duodenal ulcer patients at reduced dosage after healing of acute ulcers.
3. The treatment of **pathological hypersecretory conditions** (e.g., Zollinger-Ellison syndrome and systemic mastocytosis).
4. Short-term treatment of **active, benign gastric ulcer**. Most patients heal within 6 weeks and the usefulness of further treatment has not been demonstrated. Studies available to date have not assessed the safety of ranitidine in uncomplicated, benign gastric ulcer for periods of more than 6 weeks.
5. Treatment of **gastroesophageal reflux disease (GERD)**. Symptomatic relief commonly occurs within 1 or 2 weeks after starting therapy with Zantac 150 mg b.i.d.
6. Treatment of **endoscopically diagnosed erosive esophagitis**. Healing of endoscopically diagnosed erosive esophagitis occurs at 4 weeks (47%), 8 weeks (71%), and 12 weeks (84%) of therapy with Zantac 150 mg q.i.d. Symptomatic relief of heartburn commonly occurs within 24 hours of therapy initiation with Zantac.

Concomitant antacids should be given as needed for pain relief to patients with active duodenal ulcer, active, benign gastric ulcer, hypersecretory states; GERD; and erosive esophagitis.

CONTRAINDICATIONS: Zantac[®] is contraindicated for patients known to have hypersensitivity to the drug.

PRECAUTIONS: General: 1. Symptomatic response to Zantac[®] therapy does not preclude the presence of gastric malignancy. 2. Since Zantac is excreted primarily by the kidney, dosage should be adjusted in patients with impaired renal function (see **DOSAGE AND ADMINISTRATION**). Caution should be observed in patients with hepatic dysfunction since Zantac is metabolized in the liver.

Laboratory Tests: False-positive tests for urine protein with Multistix[®] may occur during Zantac therapy, and therefore testing with sulfosalicylic acid is recommended.

Drug Interactions: Although recommended doses of Zantac do not inhibit the action of cytochrome P-450 enzymes in the liver, there have been isolated reports of drug interactions that suggest that Zantac may affect the bioavailability of certain drugs by some mechanism as yet unidentified (e.g., a pH-dependent effect on absorption or a change in volume of distribution).

Increased or decreased prothrombin times have been reported during concurrent use of ranitidine and warfarin. However, in human pharmacokinetic studies with dosages of ranitidine up to 400 mg per day, no interaction occurred; ranitidine had no effect on warfarin clearance or prothrombin time. The possibility of an interaction with warfarin at dosages of ranitidine higher than 400 mg per day has not been investigated.

Pregnancy, Teratogenic Effects, Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at doses up to 160 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to Zantac. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers: Zantac is secreted in human milk. Caution should be exercised when Zantac is administered to a nursing mother.

Pediatric Use: Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: Headache, sometimes severe, seems to be related to Zantac[®] administration. Constipation, diarrhea, nausea/vomiting, abdominal discomfort/pain, and, rarely, pancreatitis have been reported. There have been rare reports of malaise, dizziness, somnolence, insomnia, vertigo, tachycardia, bradycardia, atrioventricular block, premature ventricular beats, and arthralgias. Rare cases of reversible mental confusion, agitation, depression, and hallucinations have been reported, predominantly in severely ill elderly patients. Rare cases of reversible blurred vision suggestive of a change in accommodation have been reported. Rare reports of reversible involuntary motor disturbances have been received.

In normal volunteers, SGPT values were increased to at least twice the pretreatment levels in 6 of 12 subjects receiving 100 mg q.i.d. intravenously for 7 days, and in 4 of 24 subjects receiving 50 mg q.i.d. intravenously for 5 days. There have been occasional reports of hepatitis, hepatocellular or hepatocanalicular or mixed, with or without jaundice. In such circumstances, ranitidine should be immediately discontinued. These events are usually reversible, but in exceedingly rare circumstances death has occurred.

Blood count changes (leukopenia, granulocytopenia, and thrombocytopenia) have occurred in a few patients. These were usually reversible. Rare cases of agranulocytosis, pancytopenia, sometimes with marrow hypoplasia, and aplastic anemia and exceedingly rare cases of acquired immune hemolytic anemia have been reported.

Although controlled studies have shown no antiandrogenic activity, occasional cases of gynecomastia, impotence, and loss of libido have been reported in male patients receiving Zantac, but the incidence did not differ from that in the general population.

Incidents of rash, including rare cases suggestive of mild erythema multiforme, and, rarely, alopecia, have been reported, as well as rare cases of hypersensitivity reactions (e.g., bronchospasm, fever, rash, eosinophilia, anaphylaxis, angioneurotic edema, and small increases in serum creatinine).

OVERDOSAGE: There has been limited experience with overdosage. Reported acute ingestions of up to 18 g orally have been associated with transient adverse effects similar to those encountered in normal clinical experience (see **ADVERSE REACTIONS**). In addition, abnormalities of gait and hypotension have been reported.

When overdosage occurs, the usual measures to remove unabsorbed material from the gastrointestinal tract, clinical monitoring, and supportive therapy should be employed.

Studies in dogs receiving dosages of Zantac[®] in excess of 225 mg/kg per day have shown muscular tremors, vomiting, and rapid respiration. Single oral doses of 1,000 mg/kg in mice and rats were not lethal. Intravenous LD₅₀ values in mice and rats were 77 and 83 mg/kg, respectively.

DOSAGE AND ADMINISTRATION: (See complete prescribing information in Zantac[®] product labeling.)

Dosage Adjustment for Patients With Impaired Renal Function: On the basis of experience with a group of subjects with severely impaired renal function treated with Zantac, the recommended dosage in patients with a creatinine clearance less than 50 mL per minute is 150 mg or 10 mL (2 teaspoonfuls equivalent to 150 mg of ranitidine) every 24 hours. Should the patient's condition require, the frequency of dosing may be increased to every 12 hours or even further with caution. Hemodialysis reduces the level of circulating ranitidine. Ideally, the dosing schedule should be adjusted so that the timing of a scheduled dose coincides with the end of hemodialysis.

May 1992

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One Of A Kind



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ranitidine HCl/Glaxo 150 mg and
300 mg tablets

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NORTH CAROLINA MEDICAL JOURNAL

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North Carolina Medical Journal

FOR DOCTORS AND THEIR PATIENTS

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On the cover: A Mini-Wright peak flow meter measures the peak rate of air exhaled and the degree of airway obstruction in patients suffering from asthma. See article on pediatric asthma in North Carolina on page 633. Photo by Malcolm Sherrin, Wayne County Community College Audiovisual/Media Center. Used with permission.

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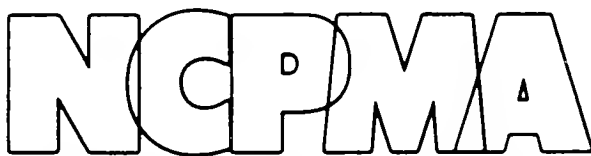
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Letters to the Editor



Fuzzy Figure

To the Editor:

I just received the November issue of the NCMJ and think it is a gem. I especially liked the final version of the "Prudent Prescribing" article, which I had reviewed for the *Journal* earlier. Your editing prowess and/or the authors' changes made the big difference.

Also I was really pleased with the article on why doctors write, or don't. I think it says something about the usefulness and interest of the *Journal*.

The article on Medicare was interesting, but Figure 1 (NC Med J 1992; 53:597) was unreadable. I wonder how the original was.

Margaret Nelsen Harker, M.D.
Chair, NCMJ Editorial Board
P.O. Drawer 897
Morehead City, NC

From the Editor:

Due to circumstances beyond our control, Figure 1 in the article "The Medicare Program: Exploring Federal Health Care Policy" (NC Med J 1992; 53:596-601) was illegible. The four figures in the article, which the author submitted as reasonably good quality, black-and-white slides, were reproduced by our printer. Unfortunately, the type in Figure 1 blurred during the separation process and could not be adequately fixed prior to presstime.

To avoid this problem, we encourage authors to submit photographs as high-quality, black-and-white glossy prints or as high-quality, color 35mm slides or glossy prints (acceptable print sizes: 5-by-7-inch or 8-by-10-inch). Prints should be labeled, but never write directly on the backs of them because ink damages the emulsion on the other side.

Relevance of the Biopsychosocial Model

To the Editor:

William Howell's take on health services research ("The Content of One Doctor's Practice: Relevance of the Biopsychosocial Model," NC Med J 1992; 53:401-9) was a welcome respite from p-values, guidelines, and outcomes. Moreover, despite a somewhat weak research design, I think the paper is a real contribution.

In reading the paper, at least four important questions come to mind. First, what impact does this approach have on patient care (process, outcome, satisfaction, etc.)? Second, how does Dr. Howell find time to do this stuff in the midst of a busy clinical practice? Third, what proportion of general internists take such an approach to patient care? Fourth, what ethical issues are raised in reaching a Balint agreement? Here, I am wondering about the extent to which the process is deceptive and/or 'paternalistic.' When is such a tack appropriate? What are the underlying assumptions about the physician-patient relationship, and are these assumptions appropriate in a changing medical marketplace (vs. clinic)? Is it appropriate to trust a 'doc in a box' to reach a Balint agreement with a patient? Enough.

Most of the responses to Dr. Howell's article addressed medical education, but what are these doctors doing in clinic? What about all those in current practice?

Jeremy Sugarman, M.D.
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Baltimore, MD 21205

Questions "Up Front" Fees

To the Editor:

Recently I have heard the phrase "up front" used. When I learned the meaning, I did not like it. I am an allergist, and when a person cannot pay for an allergy work-up, they still receive it without being charged. I've learned that this practice does not apply to all physicians when I went to refer one of these patients to another specialist. Suffering from abdominal pain, my patient was referred to a gastroenterologist. The specialist demanded money "up front." Another individual who was pregnant was told by an obstetrician that if she could not pay \$1,800 "up front" then she should go to a public health clinic.

If this is what medicine has become, it is disheartening. I have to ask: Has medicine become such a commercial transaction that we can no longer think of people's welfare? I urge physicians everywhere to remember that each patient who comes to us is a human being in need of help, and helping that person should be our first consideration, not ensuring our financial remuneration.

Claude A. Frazier, M.D.
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From the Editor:

We'd appreciate hearing from our readers about "up front" fees. Should patients pay up front so that doctors can be assured of being paid? Would patients have to pay up front for some procedures but not others? What are the ramifications of delivering health care to certain patients free of charge? How many patients could be treated for free while ensuring a medical practice remains financially secure? Anyone care to comment?

Focus on Family Practice

To the Editor:

I enjoyed Dr. Arena's article on Duke's Dr. Davison (NC Med J 1992;53:604-5). As a senior medical student at Duke University in the winter of 1962, I was interested in family practice, a position that made me rather persona non grata in the Department of Medicine. I was surprised to find that Dr. Eugene Stead, chairman of Medicine, was aware of my matching choices before I was. I was called to his office to confirm that I had selected Watts Hospital and Charlotte Memorial Hospital ahead of Duke Medical Center for my internship. Most concerned about my decision, Dr. Stead told me that I would be "dead wood in the medical profession" and would have difficulty returning to Duke Medical Center for residency. He asked me how I could have made such an error in the decision-making process. I told him that, "Of course, I did not make the decision, it was made by Dean Davison." Dean Davison

told me that he applauded my decision to enter family practice and encouraged me to get away from Duke Medical Center as fast as I could! Of course, that ended the conversation with Dr. Stead.

Fifteen years later I found myself rooming next door to Dr. Stead at a geriatrics conference at Sailor's Snug Harbor. After a dinner at the Beaufort House a large percentage of the attendees developed Salmonella gastroenteritis. In the middle of the night I heard a knock at my door. To my surprise, it was Mrs. Stead. Apparently I was one of the few people who escaped the Salmonella, and Dr. Stead clearly had not. Fortunately, I had my black bag with me and was able to give him the usual Phenergan injection and Lomotil for the diarrhea. He was remarkably improved in 12 hours.

The next night I found myself on a shrimp boat with Dr. Stead and was amazed at his resilience. Equally amazing has been his change in position to one of support of primary care over the years.

I am delighted that Dr. Daniel Blazer, dean of Medical Education, is revising Duke's mission statement to include an emphasis on primary care. Maybe family doctors are not "dead wood in the medical profession" after all.

C. Franklin Church, M.D.
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Raleigh, NC 27609

Guidelines for Letters

Letters are subject to editing and abridgment. Letters should not exceed 500 words; longer letters are welcome, however, and we will consider them for publication elsewhere in the Journal.

Letters must be typed, double-spaced, signed, dated, and include the author's phone number and address.

We do not return letters, nor do we notify authors of our intent to publish them, except in the event that we feel a letter deserves comment by the editor or another qualified expert.

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The Physician's Oath and Its Apology

J. Wesley Boyd, M.D., Ph.D.

Editor's Note: Dr. Boyd wrote this piece while completing his M.D. and Ph.D. degrees at the University of North Carolina at Chapel Hill. He graduated in June 1992 and is currently serving his psychiatric residency at The Cambridge Hospital in Cambridge, Massachusetts. Following the article are commentaries written by six North Carolina physicians whom we invited to offer their opinions on Dr. Boyd's oath. Would other readers care to respond?

The Physicians' Oath

As a physician I do solemnly swear and affirm these principles:

I. I take my central task as a physician to be alleviation of suffering, both of my patients and of society as a whole. I recognize that for different patients this may mean different things. For some, I may be required to use every power at my disposal to prevent death; for others, I may have to remove medical intervention and allow patients to die. Death will not be my absolute enemy, and I will not view death always as a failure of medicine.

At all times I will hold relief of suffering to be the highest goal of medicine, and the forestalling of death only a relative goal. Abortion, insofar as it can serve to relieve suffering (both the real, present suffering of the mother and the potential suffering of an unwanted child), I will consider the right of any pregnant woman.

II. I will strive always to better the health of my patients, intervening aggressively when appropriate on their behalf. At times, however, I will need to recognize that the best intervention might be to forego any type of medical intervention whatsoever.

I will seek the humility and the insight to recognize the limits of my own abilities, and refer patients to others when I am unable to help them.

I will not hesitate to have my treatment reviewed by my peers. Such review will ensure that I provide efficacious treatments for my patients.

I will commit myself to a lifetime of continued learning about the science of medicine. I will strive to understand and choose treatments of proven efficacy and avoid those that are unproven or unhelpful or even harmful.

I shall strive to master the non-technical aspects of medical care, acknowledging openly and without embarrassment, the powerful healing effects of my relationship with my patients. I

accept the fact that, at times, this relationship will be the most powerful therapeutic tool at my disposal.

III. I will not allow my medical practice to be dominated by monetary concerns. I vow, therefore, never to refuse treatment solely because of an individual's inability to remunerate me.

I will not accept gifts from pharmaceutical companies or others who seek my endorsement or other usage of their products unless I return these gifts to those who ultimately pay for them—my patients. I will accept drug samples from pharmaceutical companies specifically for the purpose of distributing them to patients who need them. I will not accept, however, any other gifts, large or small. I do not need to profit in this manner from my patients, for they are the ones who ultimately must pay for such gifts. My fees to patients will, to the best of my ability, reflect my actual services; I will not charge them in indirect ways such as by accepting gifts from pharmaceutical companies.

IV. I pledge myself to absolute silence regarding anything that a patient might disclose to me in the course of treatment. I will break this rule of confidence only when the well-being of others is at stake. I hope for the wisdom to choose correctly when I must break my patient's trust in this manner.

V. Before I render any service, I will inform my patient as fully as possible about the purposes of a proposed treatment, about its risks and benefits, about other treatment options. I will respect the rights of my patients, once informed, to decide for themselves whether to pursue the course I recommend, even when refusal of treatment might imply dire consequences.

VI. I will encourage people to assume responsibility for their own health and to engage in health-promoting activities. At times such a position will put me in direct conflict with certain

social mores, but I do not shrink from this responsibility. I do not shrink from assuming the role of teacher, a role implied by the title "Doctor."

VII. I will always aim to appreciate the power of diagnosis per se. Even when patients do not understand the implications of the name I attach to their ailments, I need to remember that merely rendering a diagnosis can satisfy patients' need to gain some measure of control over their problem. I will, at the same time, try to remember the potentially damaging nature of diagnosis.

VIII. I will never enter into sexual or otherwise exploitative relationships with my patients. I realize that there is often, perhaps always, a power discrepancy between doctor and patient, and that engaging in sexual relations with patients would represent the ultimate abuse of my power and would violate the deepest human and medical principles to which I subscribe.

IX. I will work toward the betterment of the health of my community as a whole. Because I believe that adequate health care is a right, I will vigorously support legislation to provide universal health care—a system in which every person, regardless of sex, race, creed, sexual preference, or social standing, has access to basic health care services. Because I hold this right to be inalienable, I will work toward implementation of such policies even if some of my freedoms as a physician (freedom to choose my patient population, freedom to charge whatever I want) might be curtailed.

In such a universal health care system, some treatment options for particular patients may be limited and some individual patients may suffer—suffering that could be alleviated were economic and physical constraints not in place—but the overall well-being of the community must take precedence over the health of particular individuals.

X. Insofar as the purpose of medicine is to improve and maintain the health of the public, I will work steadfastly for the improvement of social conditions. Broadly construed, this will require me to work to improve conditions on the planet as a whole. Because there is nothing more valuable than having a safe and healthy home, I pledge to work toward these ends regardless of their financial implications.

These principles I do affirm. May I be blessed in my work and in my life if I uphold them, and damned if I do not.

The Apology for the Physician's Oath

The oath is meant to affirm as clearly as possible a series of general principles. Given the need to cover so much territory, I could think of no other way to proceed. It cannot address every possible situation that might be encountered, although in some places it is very specific. There is much room for interpretation about how this set of principles might apply to particular cases, but nonetheless I think the code is clear enough with regard to the principles it outlines.

The oath opens with the assumption that the physician's highest goal is to alleviate suffering. This assumption is obviously controversial. Many believe that life itself is most sacred, and therefore that the preservation of life is the ultimate goal of medicine. But given the palpable reality of the suffering person, I think the oath's position is defensible.

The oath is (obviously) directed specifically at physicians, especially new physicians, but it is based on principles that extend beyond medicine and point toward a general understanding of human interaction. It asserts a communitarian rather than a strictly individualistic ethic. At times, therefore, it places

the rights and welfare of the community above the rights of the individual strictly conceived.

Those who maintain that physicians must concern themselves only with individual patients will object to this approach. They will argue that concern with the community rather than with the indi-

"The oath is (obviously) directed specifically at physicians, especially new physicians, but it is based on principles that extend beyond medicine and point toward a general understanding of human interaction."

vidual will dilute the physicians' task. Perhaps, then, this oath is a call to reevaluate the task of the physician and the role of medicine in the community.

In spite of its communitarian approach, this oath emphasizes respect for the rights of individual patients. It encourages physicians to enable (and encourage) their patients to take control of their own health. It encourages physicians to be as forthright as possible about various treatment options. It encourages physicians to respect patient decisions about treatment, even allowing patients to refuse treatment when such a refusal might be detrimental to their own health.

These goals can be achieved, in part, by understanding every patient, each of whom has a unique set of concerns and issues. It is the physician's duty to understand and "recognize" (as John Berger writes in *A Fortunate Man*) each patient sufficiently to know how to provide the best treatment. □

Acknowledgments: The author thanks Larry R. Churchill, M.D., and Nancy M.P. King, M.D., both of the Department of Social Medicine, University of North Carolina, School of Medicine, in Chapel Hill, for reading and commenting on an earlier draft of this oath.

Invited Comments on "The Physician's Oath"

By Robert W. Prichard, M.D., Member, NCMJ Editorial Board,
Department of Pathology, The Bowman Gray School of Medicine,
Wake Forest University, Winston-Salem, NC 27157-1072

I saw an earlier draft of Dr. Boyd's piece. It is a pleasure to comment on the version now going to the readers of the *Journal*. Two-and-a-half millennia ago, Hippocrates and his medical colleagues in Greece shook themselves loose from obligation to the priestly class and from dependence on divine intervention. They became free to practice and teach as their philosophy and ethics guided them. Three precepts of the traditional oath—those against abortion, against disclosure of patient confidence, and against any act not in the patient's interest—remain embedded in the way medicine is practiced today.

Dr. Boyd, without historical reference, has produced an oath that he considers appropriate to our time. In it the rights of the community become paramount, although there is emphasis on the rights of individual patients as well. In recognizing that we serve more than one master Dr. Boyd has surely gone beyond the Hippocratic school; perhaps he is being realistic as well as up-to-date. I would be interested in knowing if there is an age-related willingness to accept this fundamental philosophic departure from our Greek teachers. That is, whether some of us remain individual-patient oriented out of habit, out of our education and social/political beliefs, or because of our age; I would think the last is the case.

It is a common irony of our liberal democracy—a political arrangement that generally favors individual rights over communitarian ends—for an individual to assert the primacy of community. If Dr. Boyd's position were truly to reflect a communitarian ethic it would have to be, as was the Hippocratic Oath, confessed by members of a *community* of physicians holding common beliefs. Instead, we have what usually passes for communitarianism in our culture: a lonely voice crying in the wilderness about the need for community. Such romanticism is surely not the sole province of the young, but we must go further than Dr. Boyd does in order to have an adequate communitarian ethic, one that recognizes (rather than asserts) common values about the nature and ends of human life.

Sandel points out that "To say that the members of a society are bound by a sense of community is not simply to say that a great many of them profess communitarian sentiments and pursue communitarian aims, but rather that they conceive their identity... as defined to some extent by the community of which

they are a part. For them, community describes not just what they have as fellow citizens but also what they are..."¹ Such an ethic is, I submit, nowhere to be found on the American scene. Instead, we have fragmented convictions about what is important and meaningful. And hope for community is no substitute for having it.

Still, it is important to have periodic reflections on the value of community, not because they tell us what we share (and therefore who we are), but because they remind us of the deep divisions that remain between us. Dr. Boyd, like many in our country who are concerned about our fragmentation and heterogeneity, talks about community without appreciating how divisive are his own expressed values (such as his views on abortion, redistributionist universal health care, etc). Dr. Boyd does not so much describe a communitarian ethic as elevate his particular view of medical ethics to the status of an ethic for the whole. Those of us would do the same might profess values very different from Dr. Boyd's. Fortunately, none of us has such power, and such power cannot be acquired by rhetoric alone. That, I submit, is both the pity and the pathos of democracy.

North Carolina has a valuable resource in the Department of Social Medicine at the University of North Carolina at Chapel Hill, one that stimulates young people like Dr. Boyd and guides them in writing out their positions. We need thoughtful and well-educated people in our profession, whether we agree with them or not—apathy and resignation are more of a problem than activism. Dr. Boyd's ideas do not apply specifically to North Carolina nor do they stimulate a peculiarly Tarheel reaction. His redistributionist position is far from locally representative, and his pro-abortion stance is probably also a minority one in this state. He is, however, eminently entitled to those positions since he has taken the time to think hard, to consult mentors and to accept damnation if he violates his own principles. It scares me to think of the shape I would be in if I was damned now for much of what I believed at his age. □

Reference

- 1 Sandel M. *Liberalism and the Limits of Justice*. Cambridge: Cambridge University Press, 1982, p. 150.

Continued on next page

*By Edward C. Halperin, M.D., Deputy Editor, NCMJ,
Division of Radiation Oncology,
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Dr. Boyd's "Physician's Oath" reiterates many of the principles articulated in ancient and modern codes of medical ethics. Several areas, however, make a transition to opinions which are, in my opinion, ill-advised and potentially dangerous.

1. Dr. Boyd believes the "relief of suffering to be the highest goal of medicine, and the forestalling of death only a relative goal. Abortion, insofar as it can serve to relieve suffering (both the real, present suffering of the mother and the potential suffering of an unwanted child), I will consider the right of any pregnant women." This curious statement requires some consideration. I do not know what a "relative" goal is. Relative to what? I suspect that Dr. Boyd means that the goal of forestalling is a secondary to the relief of suffering. What sort of suffering? Physical suffering? Mental suffering? Financial suffering? Some of each? If Dr. Boyd accepts mental or financial factors as components of suffering, would he say that forestalling death should be subsidiary to the price of medical care or to short-term emotional distress? I hope not.

2. Most people who support the "right" to abortion confine this right to the first and, perhaps, the early second trimester of pregnancy. Dr. Boyd makes no such distinction. And he uses an extraordinary argument to support abortion—that the aborted fetus will avoid the potential suffering of being unwanted. Since Dr. Boyd believes that no scientific or spiritual evidence tells us the exact moment when "actual human life begins" (borrowing an expression from the late Senator John East), then he can feel comfortable with early-pregnancy abortion—as many citizens do. But it seems outrageous to use the prevention of "potential suffering" as a justification for abortion. The invocation of potential suffering as a justification for abortion is a "slippery slope" philosophical argument—who else's potential suffering justifies death? The physically handicapped? The mentally

retarded? The dispossessed? We have, unfortunately, seen people killed in recent memory because someone deemed their state in life "unworthy." I respect Dr. Boyd's right to favor abortion, but his justification is flawed, convoluted, and simply wrong.

3. In Section IX, Dr. Boyd states: "the overall well-being of the community must take precedence over the health of particular individuals." I hope that he will post this view on his office door so that his patients will know that they are about to see a doctor who has concerns that override their personal well-being! What does this extraordinary assertion mean? Would Dr. Boyd not push the system to dialyze a poor person because the financial drain on society might be too great? (And who will decide the definition of "too great?") Dr. Boyd recognizes that "treatment options for particular patients may be limited and some individual patients may suffer," but does he really not believe that physicians should try to move heaven and earth to do what's best for the individual patient even if some health economist or politician says it's "too expensive"? Should the elderly be denied treatment of inoperable lung cancer? Should children with Down's Syndrome not have their congenital heart defects or leukemias treated because the "well-being of the community" takes precedence? A society might make such judgments through its political system, but I would argue that individual physicians have an overriding obligation to their patients.

Dr. Boyd's oath is not really "a call to reevaluate the task of the physician" as he suggests in his "apology." It is really a call to establish the definition of a different profession—some sort of social engineer disguised in a white coat. He will have to adopt a different name than that of a physician. That name is already taken by a profession with higher goals. □

*By Assad Meymandi, M.D., Medical Director
Cape Fear Neuropsychiatric Associates, Fayetteville, NC 28304*

Dr. Boyd is to be congratulated for his efforts to define the job of the physician. In our legalistic, pluralistic, moralistic, technocratic, and litigious society, we do need to define ourselves as clearly as possible—then to redefine who we are and what we do. I think Dr. Boyd has attempted to do just that. However, we

should not make his stand the code of conduct for all of us. Let me elaborate:

In my own daily practice, I see many patients, especially elderly patients, who suffer from iatrogenic drug addiction and polypharmacy. I am sure that the physicians who prescribed

those medications hoped to relieve suffering, but they ended up causing more suffering than they relieved. Similarly, abortion seems to me the wrong way to relieve the "suffering" of an anxious woman with an unwanted pregnancy. Dr. Boyd needs to think through how he would define the word "suffering," before he commits himself to the job of alleviating it. My dictionary says "suffer" derives from the Latin root "sufferre," which means "to bear up" and "to tolerate." Suffering is not that bad, if one knows how to manage and cope. Perhaps Dr. Boyd means that the acquisition of coping skills is part of his strategy to relieve suffering. We need to define "suffering" and a myriad of other words before using them in a text that reflects our credo.

I turn now to another issue: The monetary concerns of medical practice. I was chatting in the doctors' lounge with a Ob/Gyn colleague who has closed much of his practice because of fear of litigation. This is not a man of greed. I know that he has delivered many babies free of charge, has even assisted, in some instances, with the education of those babies. Now my colleague refuses medical service to patients because of our abominable and scary medico-legal climate (more than 18.4 million civil suits filed in state courts in 1990, up 13% in just six years), the result and cause of our lunatic proliferation of lawyers (from 260,000 in 1960 to 760,000 today). Before Section III of Dr. Boyd's Oath can be fully implemented, the fear of litigation must be addressed and ameliorated.

Dr. Boyd's article did send me to the encyclopedia to revisit the Hippocratic Oath. I recalled that 2,300 years ago all wisdom and knowledge in medicine was described as emanat-

ing from one man. Now we live in an era where many thoughtful, knowledgeable, motivated, and altruistic individuals like Dr. Boyd can make a contribution to the betterment of mankind. Nonetheless, I argue with the author about his use, in Section VII, of the word diagnosis. Giving omnipotence to a word or label or CPT code is detrimental to the patient. "Diagnosis" derives from the Greek "dia," meaning "thorough," and "gnosis," meaning "knowledge." The word diagnosis implies a thorough knowledge of the patient and of the patient's biopsychosocial make-up, constitution, interaction, and dynamics. It is not a mere label or a code. As physicians, we must get to know (diagnose) our patients. Ultimately we must come to a consensus as to how physicians can gain "thorough knowledge" when they operate under such constraints as having only seven minutes allotted for a visit. As a group we have not even begun to think along these lines.

I personally believe that access to health care is a basic human right, part of the preamble to the U.S. Constitution. But I do not believe any one person, or a body of professionals, can assert such a right unless the matter has been debated thoroughly through an elaborate and exhaustive political process. The level of debate and the tone of the argument may be defined and guided by the professionals; but the process should be one of public scrutiny and political consensus. I believe that out of such an exhaustive crucible of examination would emerge a worthwhile document. I commend Dr. Boyd for starting such a process, even if he may not have meant to do so! □

*By William B. Blythe, M.D., NCMJ Associate Editor and Editorial Board Member,
Marion Covington Professor of Medicine, Division of Nephrology,
The University of North Carolina School of Medicine, Chapel Hill, NC 27599-7155*

I am delighted to have been asked to comment on "The Physician's Oath and Its Apology," which was written by my friend, colleague, and former student, J. Wesley Boyd. My reaction to the essay is perhaps colored by the fact that I know Wes to be bright, thoughtful, and completely dedicated to serving us all.

My knowing Wes leads me to my most immediate and, at the same time, most lasting impression of *his* contemporaneous oath, and that is Doctor Boyd's inner compulsion to do what is best for the patient as is summarized in the last sentence of the essay, "It is the physician's duty to understand and 'recognize' each patient sufficiently to know how to provide the best treatment."

In general, I agree with Doctor Boyd's "Physician's Oath" and find it to be an eloquent and elegant statement as to what a doctor should be. However, in my judgment, it is a bit too personalized. For example, I agree completely with Doctor

Boyd's belief concerning abortion but at the same time realize that there may be equally dedicated and competent physicians who hold otherwise.

Furthermore, I am inclined to disagree with his "communitarian" approach. I want my doctor—as I want my lawyer—to hold my interests more sacred than that of the community. I suspect that they are not at odds most of the time, anyway.

Finally, when Wes Boyd writes "These principles I do affirm. May I be blessed in my work and in my life if I uphold them, and damned if I do not," I know that he has thought deeply about the matter and means what he says. He is not alone in the recent graduating medical classes, and that fact perhaps more than any other makes me sanguine about the future of our profession. □

Continued on next page

By Elizabeth P. Kanof, M.D.

Raleigh Dermatology Associates, P.A., Raleigh, NC 27609

The Physician's Oath proposed by Dr. Boyd is interesting, provocative, and useful. It challenges all physicians to thoughtfully consider the issues thrust upon us by the miracles and dilemmas of modern technology. Furthermore, society turns to the medical profession for guidance regarding the ethical issues addressed. We physicians need to actively debate these issues and propose guidelines for change when indicated. Should we fail to fulfill this responsibility, others will make decisions for us, and we will find ourselves in a perpetual reactive, rather than proactive, role.

Some of the proposed statements are obviously more controversial than others. Until we are able to reach a consensus of opinion on the issue of abortion, any oath adopted by physicians would need to reflect the individual doctor's right to follow his or her own conscience regarding this issue.

The first sentence of Section IX states a goal that is not controversial and is likely to be endorsed by all of us. However, in my opinion, it would be a mistake at this time to voluntarily surrender the freedoms stated as examples. We are already overburdened by too many controls. We need to champion what is best for our patients; to achieve this we need to preserve our autonomy and to think and act on their behalf as we feel best.

When principles are derived from a consensus of informed and compassionate consideration they can be affirmed because they stand on their own merit. The last sentence is redundant and may be offensive.

The proposed Physician's Oath needs no apology and should prove useful to physicians as we reassess our responsibilities in a changing world. □

By W. Randolph Chitwood, Jr., M.D., Professor and Chair

Division of Cardiothoracic Surgery

East Carolina University School of Medicine, Greenville, NC 27858

The "Physician's Oath," proposed by Dr. Boyd, represents a nearly all-encompassing list of moral and ethical "dos and don'ts" for the modern physician. Although I respect the honest attempt to modernize the tenets set forth in the "Hippocratic Oath," Dr. Boyd has defined the nature of ethical living too narrowly. This is a personalized oath that will not be considered by most physicians. It is a compendium, broaching many sensitive religious, moral, ethical, and political issues. Economic issues have forced physicians to define practice standards more rigidly by HCFA, PPRC, OSHA, CPT, ICD-9, and DRG guidelines. Because of these, are our patients better off than when my father practiced medicine three decades ago? Probably not. Ethical issues require broad interpretation and not the sharp edge of definition.

Boyd's choice of relief of suffering as the sentinel goal of medicine defines the profession too selectively. Moreover, an emphasis on withholding treatment, rather than treating, makes euthanasia nearly mandatory to relieve *all* suffering. I do not believe that this is the author's overall intent, but this "Oath" could be interpreted in this dangerous manner. The debate over abortion is far from settled and to include this in an "Oath" may make it a medical duty rather than an ethical decision.

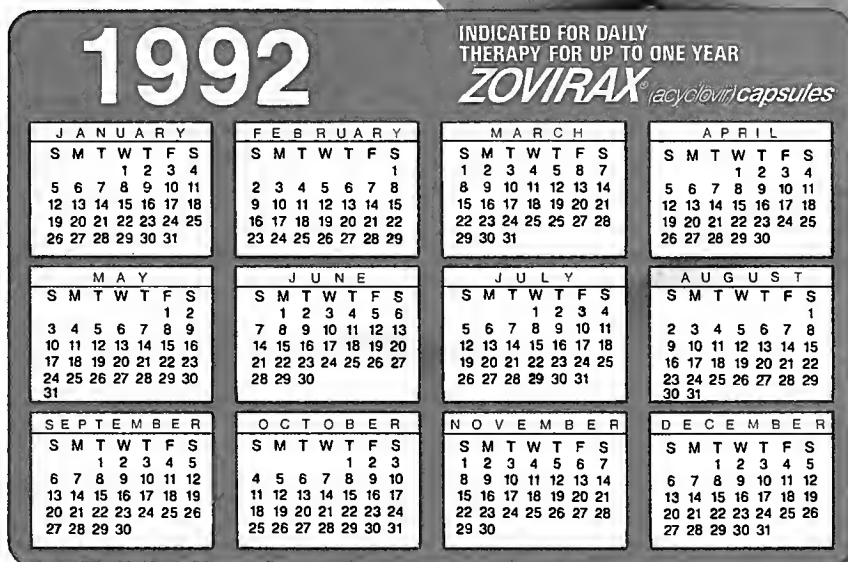
The discussion regarding accepting gifts and samples from

pharmaceutical companies is verbose and "elastic." Is it permissible to be influenced when these gifts are given to the poor alone? The inclusion of such a statement is to restate the obvious. In treating the *individual* patient, physicians should not be influenced by factors other than medical and mental needs. In a recent address to the American Osler Society, Dr. Edmund D. Pellegrino, a leading medical ethicist, suggested that the falling societal status of our profession has resulted, in large part, from decreasing self-effacement of physicians. It is intuitive that physicians must distance themselves from outside influences.

The "Oath" considers a universal health care system a right. Most physicians believe that all patients deserve medical care and that a single standard of care must be provided. However, to define health care policy and legislative support in a credo of ethics detracts from the intent and indeed is not catholic in nature. Lastly, the patient-physician relationship has been predicated on a bond of individual trust. This relationship cannot be maintained in a matrix of reason that suggests the physician may need to forsake his or her individual patient for the good of many.

Continued on page 662

ANNOUNCING A GREAT YEAR AHEAD FOR GENITAL HERPES PATIENTS



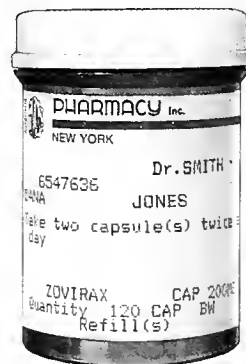
1-YEAR INDICATION FOR DAILY THERAPY

Genital herpes patients can look forward to a great year ahead. Results of a recent clinical study show a lesion-free year for nearly half the patients treated with ZOVIRAX Capsules 400 mg b.i.d.*¹ For all ZOVIRAX Capsule recipients, recurrences during the study year were limited to a mean of 1.8, compared with a mean of 11.4 for placebo recipients.¹

Daily use was also shown to be well tolerated. And this extended clinical study demonstrated no evidence of cumulative toxicity and no change in acyclovir sensitivity.^{1,2}

An appropriate patient profile for continuous suppressive therapy would include the patient with frequent recurrences (6 or more outbreaks per year); the patient with severe recurrences; and the patient emotionally impaired by genital herpes recurrences.

Prescribe daily ZOVIRAX Capsule therapy...and help keep your patients lesion-free longer.[†]



ZOVIRAX® 200mg
(acyclovir) Capsules

KEEPS GENITAL HERPES PATIENTS LESION-FREE LONGER[†]

*Alternate maintenance regimens range from 200 mg t.i.d. to 200 mg five times daily.

[†]In a controlled study of 3 years' duration, 45%, 52%, and 63% of patients remained free of recurrences in the first, second, and third years, respectively.³

Please see brief summary of prescribing information on adjacent page.

ZOVIRAX® CAPSULES ZOVIRAX® TABLETS ZOVIRAX® SUSPENSION (ACYCLOVIR)

BRIEF SUMMARY

CONTRAINDICATIONS: Zovirax Capsules, Tablets, and Suspension are contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulations. **WARNINGS:** Zovirax Capsules, Tablets, and Suspension are intended for oral ingestion only. **PRECAUTIONS: General:** Zovirax has caused decreased spermatogenesis at high parenteral doses in some animals and mutagenesis in some acute studies at high concentrations of drug (see PRECAUTIONS—Carcinogenesis, Mutagenesis, Impairment of Fertility). The recommended dosage should not be exceeded. Exposure of herpes simplex and varicella-zoster isolates to acyclovir *in vitro* can lead to the emergence of less sensitive viruses. The possibility of the appearance of less sensitive viruses in man must be borne in mind when treating patients. The relationship between the *in vitro* sensitivity of herpes simplex or varicella-zoster virus to acyclovir and clinical response to therapy has yet to be established (see full prescribing information). Because of the possibility that less sensitive virus may be selected in patients who are receiving acyclovir, all patients should be advised to take particular care to avoid potential transmission of virus if active lesions are present while they are on therapy. In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of acyclovir may result in selection of resistant viruses which may not fully respond to continued acyclovir therapy. Caution should be exercised when administering Zovirax to patients receiving potentially nephrotoxic agents since this may increase the risk of renal dysfunction. **Drug Interactions:** Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were correspondingly reduced. The clinical effects of this combination have not been studied. **Carcinogenesis, Mutagenesis, Impairment of Fertility:** The data presented below include references to peak steady state plasma acyclovir concentrations observed in humans treated with 800 mg given orally 6 times a day (dosing appropriate for treatment of herpes zoster) or 200 mg given orally 6 times a day (dosing appropriate for treatment of genital herpes). Plasma drug concentrations in animal studies are expressed as multiples of human exposure to acyclovir at the higher and lower dosing schedules (see full prescribing information). Acyclovir was tested in lifetime bioassays in rats and mice at single daily doses of up to 450 mg/kg administered by gavage. There was no statistically significant difference in the incidence of tumors between treated and control animals, nor did acyclovir shorten the latency of tumors. At 450 mg/kg/day, plasma concentrations were 3 to 6 times human levels in the mouse bioassay and 1 to 2 times human levels in the rat bioassay. Acyclovir was tested in two *in vitro* cell transformation assays. Positive results were observed at the highest concentration tested (31 to 63 times human levels) in one system and the resulting morphologically transformed cells formed tumors when inoculated into immunosuppressed, syngeneic, weanling mice. Acyclovir was negative (40 to 80 times human levels) in the other, possibly less sensitive, transformation assay. In acute cytogenetic studies, there was an increase, though not statistically significant, in the incidence of chromosomal damage at maximum tolerated parenteral doses of acyclovir (100 mg/kg) in rats (62 to 125 times human levels) but not in Chinese hamsters; higher doses of 500 and 1000 mg/kg were clastogenic in Chinese hamsters (380 to 760 times human levels). In addition, no activity was found after 5 days dosing in a dominant lethal study in mice (36 to 73 times human levels). In all 4 microbial assays, no evidence of mutagenicity was observed. Positive results were obtained in 2 of 7 genetic toxicity assays using mammalian cells *in vitro*. In human lymphocytes, a positive response for chromosomal damage was seen at concentrations 150 to 300 times the acyclovir plasma levels achieved in man. At one locus in mouse lymphoma cells, mutagenicity was observed at concentrations 250 to 500 times human plasma levels. Results in the other five mammalian cell loci follow: at 3 loci in a Chinese hamster ovary cell line, the results were inconclusive at concentrations at least 1850 times human levels; at 2 other loci in mouse lymphoma cells, no evidence of mutagenicity was observed at concentrations at least 1500 times human levels. Acyclovir has not been shown to impair fertility or reproduction in mice (450 mg/kg/day, p.o.) or in rats (25 mg/kg/day, s.c.). In the mouse study plasma levels were 9 to 18 times human levels, while in the rat study they were 8 to 15 times human levels. At a higher dose in the rat (50 mg/kg/day, s.c.), there was a statistically significant increase in post-implantation loss, but no concomitant decrease in litter size. In female rabbits treated subcutaneously with acyclovir subsequent to mating, there was a statistically significant decrease in implantation efficiency but no concomitant decrease in litter size at a dose of 50 mg/kg/day (16 to 31 times human levels). No effect upon implantation efficiency was observed when the same dose was administered intravenously (53 to 106 times human levels). In a rat peri- and postnatal study at 50 mg/kg/day s.c. (11 to 22 times human levels), there was a statistically significant decrease in the group mean numbers of corpora lutea, total implantation sites and live fetuses in the F₁ generation. Although not statistically significant, there was also a dose-related decrease in group mean numbers of live fetuses and implantation sites at 12.5 mg/kg/day and 25 mg/kg/day, s.c. The intravenous administration of 100 mg/kg/day, a dose known to cause obstructive nephropathy in rabbits, caused a significant increase in fetal resorptions and a corresponding decrease in litter size (plasma levels were not measured). However, at a maximum tolerated intravenous dose of 50 mg/kg/day in rabbits (53 to 106 times human levels), no drug-related reproductive effects were observed. Intraperitoneal doses of 80 or 320 mg/kg/day acyclovir given to rats for 6 and 1 months, respectively, caused testicular atrophy. Plasma levels were not measured in the one month study and were 24 to 48 times human levels in the six month study. Testicular atrophy was persistent through the 4-week postdose recovery phase after 320 mg/kg/day; some evidence of recovery of sperm production was evident 30 days postdose. Intravenous doses of 100 and 200 mg/kg/day acyclovir given to dogs for 31 days caused aspermatogenesis. At 100 mg/kg/day plasma levels were 47 to 94 times human levels, while at 200 mg/kg/day they were 159 to 317 times human levels. No testicular abnormalities were seen in dogs given 50 mg/kg/day i.v. for one

month (21 to 41 times human levels) and in dogs given 60 mg/kg/day orally for one year (6 to 12 times human levels). **Pregnancy: Teratogenic Effects:** Pregnancy Category C. Acyclovir was not teratogenic in the mouse (450 mg/kg/day, p.o.), rabbit (50 mg/kg/day, s.c. and i.v.) or in standard tests in the rat (50 mg/kg/day, s.c.). These exposures resulted in plasma levels 9 and 18, 16 and 106, and 11 and 22 times, respectively, human levels. In a non-standard test in rats, there were fetal abnormalities, such as head and tail anomalies, and maternal toxicity. In this test, rats were given 3 s.c. doses of 100 mg/kg acyclovir on gestation day 10, resulting in plasma levels 63 and 125 times human levels. There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. Although acyclovir was not teratogenic in standard animal studies, the drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination. **Nursing Mothers:** Acyclovir concentrations have been documented in breast milk in two women following oral administration of Zovirax and ranged from 0.6 to 4.1 times corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg/day. Caution should be exercised when Zovirax is administered to a nursing woman. **Pediatric Use:** Safety and effectiveness in children less than 2 years of age have not been adequately studied. **ADVERSE REACTIONS—Herpes Simplex: Short-Term Administration:** The most frequent adverse reactions reported during clinical trials of treatment of genital herpes with orally administered Zovirax were nausea and/or vomiting in 8 of 298 patient treatments (2.7%) and headache in 2 of 298 (0.6%). Nausea and/or vomiting occurred in 2 of 287 (0.7%) patients who received placebo. Less frequent adverse reactions, each of which occurred in 1 of 298 patient treatments with orally administered Zovirax (0.3%), included diarrhea, dizziness, anorexia, fatigue, edema, skin rash, leg pain, inguinal adenopathy, medication taste and sore throat. **Long-Term Administration:** The most frequent adverse reactions reported in a clinical trial for the prevention of recurrences with continuous administration of 400 mg (two 200 mg capsules) 2 times daily for 1 year in 586 patients treated with Zovirax were: nausea (4.8%), diarrhea (2.4%), headache (1.9%) and rash (1.7%). The 589 control patients receiving intermittent treatment of recurrences with Zovirax for 1 year reported diarrhea (2.7%), nausea (2.4%), headache (2.2%) and rash (1.5%). The most frequent adverse reactions reported during the second year by 390 patients who elected to continue daily administration of 400 mg (two 200 mg capsules) 2 times daily for 2 years were headache (1.5%), rash (1.3%) and paresthesia (0.8%). Reactions reported by 329 patients during the third year include asthenia (1.2%), paresthesia (1.2%) and headache (0.9%). **Herpes Zoster:** The most frequent adverse reactions reported during three clinical trials of treatment of herpes zoster (shingles) with 800 mg of oral Zovirax 5 times daily for 7 to 10 days in 323 patients were: malaise (11.5%), nausea (8.0%), headache (5.9%), vomiting (2.5%), diarrhea (1.5%) and constipation (0.9%). The 323 placebo recipients reported malaise (11.1%), nausea (11.5%), headache (11.1%), vomiting (2.5%), diarrhea (0.3%) and constipation (2.4%). **Chickenpox:** The most frequent adverse events reported during three clinical trials of treatment of chickenpox with oral Zovirax in 495 patients were: diarrhea (3.2%), abdominal pain (0.6%), rash (0.6%), vomiting (0.6%), and flatulence (0.4%). The 498 patients receiving placebo reported: diarrhea (2.2%), flatulence (0.8%), and insomnia (0.4%). **Observed During Clinical Practice:** Based on clinical practice experience in patients treated with oral Zovirax in the U.S., spontaneously reported adverse events are uncommon. Data are insufficient to support an estimate of their incidence or to establish causation. These events may also occur as part of the underlying disease process. Voluntary reports of adverse events which have been received since market introduction include: **General:** fever, headache, pain, peripheral edema **Digestive:** diarrhea, elevated liver function tests, gastrointestinal distress, nausea **Hemic and Lymphatic:** leukopenia, lymphadenopathy **Nervous:** confusion, dizziness, hallucinations, paresthesia, somnolence **Musculoskeletal:** myalgia **Skin:** alopecia, pruritus, rash, urticaria **Special Senses:** visual abnormalities

February 1992

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References: 1. Mertz GJ, Jones CC, Mills J, et al. Long-term acyclovir suppression of frequently recurring genital herpes simplex virus infection: a multicenter double-blind trial. *JAMA*. 1988;260:201-206. 2. Mertz GJ, Eron L, Kaufman R, et al. Prolonged continuous versus intermittent oral acyclovir treatment in normal adults with frequently recurring genital herpes simplex virus infection. *Am J Med*. 1988;85(suppl 2A):14-19. 3. Data on file, Burroughs Wellcome Co., 1992.

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IMPROVING LIVES THROUGH
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The *North Carolina Medical Journal* is a medium for communication with and by members of the medical community of this state. The *Journal* will consider for publication articles relating to and illuminating medical science, practice, and history; editorials and opinion pieces; letters; personal accounts; poetry and whimsical musings; and photographs and drawings. Papers that relate to the present, past, or future practice of the health professions in North Carolina are especially pertinent, but manuscripts reflecting other perspectives or topics are welcomed. Prospective authors should feel free to discuss potential articles with the editors.

Manuscript Preparation

Authors should submit papers prepared according to the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (N Engl J Med 1991;324:424-8) with the following exceptions: 1) no abstract is needed for an article; 2) no running title is needed; and 3) measurements must be reported in metric units, but use of the International System of Units (SI) is optional.

To summarize major elements: Submit two copies of text (including Letters to the Editor), double-spaced typed with one-inch margins, on one side of each sheet of paper. Title page should include addresses, and telephone and facsimile numbers of the corresponding author. Authors may submit a cover letter and a 3 1/2- or 5 1/4-inch floppy computer disc containing the text written in MS DOS compatible format (WordPerfect, Microsoft Word, Displaywrite, or ASCII).

Submit illustrations, in duplicate, in the form of high-quality color 35mm slides or 5-by-7-inch or 8-by-10-inch glossy photographs, or as black-and-white glossy prints (5-by-7-inch or 8-by-10-inch). Label all illustrations with author's name, number them sequentially according to their position in the text, and indicate the orientation of the images, if necessary. *Do not write directly on the backs of prints.*

Type figure legends, double-spaced, on a separate sheet of paper. Tables should be typed, double-spaced, one to a single sheet of paper. All tables must have titles and consecutive Arabic numbers.

Keep references to a minimum (no more than 15, preferably 10 or fewer), retaining those that document

important points. The "Uniform Requirements" cited earlier contain the format for references. Authors are responsible for the accuracy and pertinence of all citations.

Avoid abbreviations entirely if possible; keep them to a minimum if not. When used, completely define abbreviations at the first point of usage in the text.

Manuscript Editing

A medically qualified editor reads all manuscripts and, in most instances, sends them out for further review by one or more other members of the North Carolina Medical Society. Manuscripts are received with the understanding that they are not under review or consideration for publication elsewhere. Decisions to publish or not are made by the editors, advised by the peer reviewers.

We encourage a relatively informal writing style since we believe this improves communication. Imagine yourself talking with your unseen audience—as long as this doesn't lead you to scientific or linguistic inaccuracy. Be brief, clear, simple, and precise.

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REMEMBER

1975?

JANUARY 1 H.R. HALDEMANN, JOHN C. MITCHELL AND JOHN D. EHRLICHMAN, FORMER TOP AIDES OF PRESIDENT RICHARD NIXON, ARE CONVICTED OF CONSPIRACY TO OBSTRUCT JUSTICE IN THE WATERGATE CASE. **FEBRUARY 11** MARGARET THATCHER IS ELECTED LEADER OF THE CONSERVATIVE PARTY, BECOMING THE FIRST WOMAN TO HEAD A BRITISH POLITICAL PARTY. **APRIL 30** THE SOUTH VIETNAMESE GOVERNMENT SURRENDERS TO THE COMMUNISTS, ENDING THE WAR IN VIETNAM. ♦ **SEPTEMBER 29** THE MALPRACTICE SITUATION IN NORTH CAROLINA REACHES A CRISIS AFTER THE LAST COMMERCIAL INSURANCE COMPANY ANNOUNCES IT WILL NO LONGER PROVIDE MALPRACTICE COVERAGE IN THE STATE. ♦ **OCTOBER 1** IN MANILA, MUHAMMED ALI DEFEATS JOE FRAZIER IN THE FIFTEENTH ROUND TO RETAIN THE WORLD HEAVY-WEIGHT BOXING TITLE. ♦ **OCTOBER 23** NORTH CAROLINA PHYSICIANS CREATE A MUTUAL INSURANCE COMPANY TO ASSURE A STABLE, FAIR PROFESSIONAL LIABILITY MARKET. ♦ THE YEAR'S TOP FILMS INCLUDE *JAWS*, *ONE FLEW OVER THE CUCKOO'S NEST*, AND *NASHVILLE*.

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Managing Pediatric Asthma in North Carolina

Rubin F. Maness, M.D.

Asthma has been known since ancient times, but the exact cause is unknown and there is no cure. Asthma is becoming more common and, despite therapeutic advances, mortality rates are rising. Nevertheless, we have a tremendous amount of new information available to improve asthma control and to lessen morbidity and mortality. I review some of that information here, hoping to enhance your ability and confidence in the care and education of the patient with asthma.

What is Asthma?

"Asthma" comes from the Greek word for "panting." It is a disease characterized by recurrent airway narrowing (obstruction) that is reversible either spontaneously or with treatment. Airway narrowing impedes the flow of air through the bronchi. There are two important components to this narrowing: 1) hyperreactivity or increased airway responsiveness to a variety of stimuli and 2) inflammation. Hyperreactivity is especially important in the early phases of an asthma episode when smooth muscles surrounding the airway constrict causing acute narrowing. Acute smooth muscle spasm

is usually readily reversible, but remember, a 50% reduction in airway diameter causes a 16-fold increase in resistance to air flow! Therefore, even small changes in airway caliber significantly affect the work of breathing. The second component of airway narrowing is due to inflammation, and this is especially important in the late phase of an asthma episode when, after several hours, there is swelling of the airway wall due to edema and an influx of inflammatory cells. When the stimulus is severe or persistent or if inflammation is not adequately treated, airway edema and associated mucus plugging can lead to total airway obstruction.

Symptoms, Signs, and Diagnosis

Symptoms of asthma usually include cough (which may be the only symptom of mild asthma), shortness of breath, and increased mucus production. Children often complain of abdominal pain and nausea. During moderately severe episodes there may be tachypnea, intercostal retractions, wheezing, and a prolonged expiratory phase, while severe episodes may have supraclavicular retractions, cyanosis, decreased breath sounds with diminished or absent wheezing, an anxious, agitated appearance, or lethargy. The last of these are signs of late respiratory failure and require immediate intervention.

Asthma is diagnosed when the patient has had more than one episode of reversible airway narrowing. Thus, children who wheeze during more than a single illness have asthma. It is to the patient's benefit to make the diagnosis after the second or certainly by the third episode. Deferring the diagnosis deprives the family of the opportunity to learn about asthma and to control the disease. All patients diagnosed with asthma should have a baseline chest x-ray, and those age five or older should have confirmatory pulmonary function testing.

Prevalence

At least 10 million persons in the U.S. have asthma; three to five million are children. More than 70,000 North Carolina children have asthma. While the overall prevalence is about 4%, asthma is more common in children (10% of young school-age boys, falling to 6% by teenage years; 6% of girls). Asthma is the most common chronic disease of childhood. Data from the Centers for Disease Control show a 29% increase in asthma prevalence between 1980 and 1987.¹

Morbidity and Mortality

Asthma causes more school absences than any other chronic disease. More than 10 million school days are missed per year in the U.S. due to asthma.

Dr. Maness is vice president of the American Lung Association of NC and chairman of the Joint ALANC-NC Thoracic Society Committee on Asthma. His address is Goldsboro Pediatrics, PA, 2706 Medical Office Place, Goldsboro 27534.

Table 1. Asthma treatment goals.

1. Prevention of acute exacerbations requiring emergency care or hospitalizations.
2. Control of symptoms including those that interfere with a full night's sleep.
3. Normal activity levels including regular school attendance and participation in competitive sports if desired.
4. Maintenance of pulmonary function as close to normal as possible.
5. Avoidance of unnecessarily complicated treatment regimens and adverse effects of asthma medications.¹

Unfortunately, the number of deaths due to asthma have risen dramatically in recent years. In 1976 there were 2,000 deaths of which 60 were in children under 15 years old; in 1986 there were 4,000 deaths and 120 were children under 15 years old.² Deaths continue to increase by about 10% per year. Mortality among black children ages 10 to 14 is up to nine times higher for than others with asthma.

The causes of increasing mortality are multifactorial but failure to adequately diagnose the disease or to educate patients and their families contributes substantially.² Overreliance on beta 2-agonist drugs and theophylline without adequate anti-inflammatory medication may allow an insidious decline in pulmonary function. The stage is then set for an additional trigger to provoke a fatal episode. We need to emphasize the use of maintenance anti-inflammatory medications for those with chronic symptoms.

Patients, parents, and physicians often fail to recognize the severity of potentially fatal asthma episodes. Objective monitoring of peak flow rates can detect an early decline in pulmonary function and allow early intervention by adjusting both bronchodilators and anti-inflammatory medications. Many mild or moderate exacerbations can be reversed without systemic corticosteroids.³ Monitoring can detect episodes of significant bronchodilator subresponsiveness, allowing the use of short courses of systemic steroids to avoid severe exacerbations. Objective monitoring has fantastic potential for reducing both morbidity and mortality!

Prognosis

Mortality due to asthma is rising, but the risk that a given child will die during an asthma episode is small, especially with good management. Parents sometimes expect their child to "outgrow" their asthma quickly. This may lead to failure of compliance with appropriate maintenance therapy. The planned duration of maintenance and indications for tapering or discontinuing therapy should be discussed with the parents.

It is true that 25% to 75% of patients have no asthma symptoms requiring medication 10 to 20 years after the onset of their illness. Study results vary based on severity and age at entry. In general, about 50% of children with asthma will no longer have symptoms by adulthood. Sensitive airways may still be detected by bronchial provocation testing however, even in asymptomatic individuals.

More Help and Hope for the '90s

Increasing prevalence, morbidity, and mortality has prompted the American Academy of Allergy and Immunology, the American College of Chest Physicians, The American Lung Association, The American Thoracic Society, and the National Institutes of Health to designate asthma as their number one priority for the 1990s. In 1989, the National Heart, Lung, and Blood Institute convened an expert panel on the Management of Asthma and issued its *Guidelines for the*

Diagnosis and Management of Asthma in August 1991. This comprehensive 136-page report covers all facets of asthma and is must reading for all physicians interested in asthma. The *Executive Summary* (essential information in 44 pages), publication number 91-3042A, or the full report, publication number 91-3042, may be obtained from the National Asthma Education Program (NAEP), National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD 20892.

Management of Asthma

While there is at present no cure, asthma can be controlled. Asthma treatment goals (Table 1) are achieved through three integral components: patient education, environmental control, and medication.¹

Patient Education. Patients need to know the basics of asthma pathophysiology, how to recognize an asthma episode, the signs of respiratory distress, triggers and their avoidance, and asthma medications. Parents should be taught to recognize the physical signs of respiratory distress. Classification as to mild, moderate, or severe distress may be facilitated by using Dr. Thomas Plaut's guide to "Assessing the Symptoms and Severity of an Asthma Attack," (see page at right) which may be copied and given to the patient. The physician may supplement this by listing respiratory rates specific for age. Parents are then equipped to accurately describe their child's status to the physician. Patients five years or older should be introduced to peak flow monitoring. Written instructions for routine medications and written emergency plans are essential. Additional resources for patient education are listed in Appendix A.

Environmental Control. Environmental factors that initiate bronchospasm and inflammation are known as asthma triggers. The most common triggers for infants and young children are viral respiratory infections. Mycoplasma infections are significant triggers for school-age

A GUIDE FOR PARENTS

Assessing the symptoms and severity of an asthma attack

Once you learn the different breathing patterns characteristic of a mild, moderate, or severe asthma attack, you will be better equipped to provide the type of information your doctor needs to prescribe the best treatment for your child. In fact, if you learn to pick up on early symptoms of an attack, you may be able to take the appropriate steps to control the attack before it worsens. Remember, treatment is most effective if it is not delayed.

Inhalation/Expiration Ratio

This ratio measures how long it takes to *breathe in* (inhalation) as compared to *breathing out* (expiration). When we breathe normally, breathing in takes twice as long as breathing out. During an asthma attack, it takes *longer* for the child to exhale.

Mild

You hardly notice a difference between breathing in and breathing out.



Moderate

The time it takes to breathe in is *equal* to the time it takes to breathe out.



Severe

Breathing out takes *longer* than breathing in.



Your Doctor's Special Comments

Adapted from Dr. Thomas F. Plaut's book *Children With Asthma: A Manual for Parents*, with permission of Pedipress, Inc.

Wheezing

This indicates difficulty in breathing, whereby air is flowing through very constricted bronchial tubes, causing a "whistling" sound.



Mild

Wheezing is noticeable when the child has just about finished exhaling.

Moderate

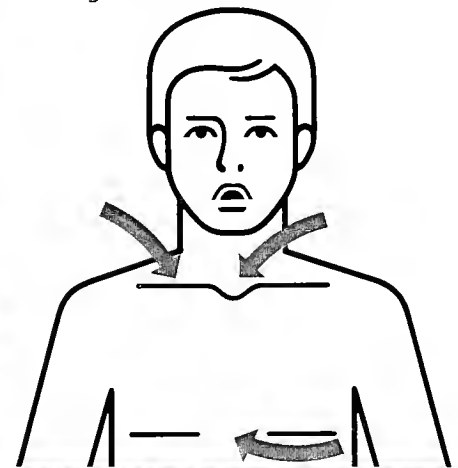
Wheezing is apparent throughout the entire breathing-out phase. Eventually the wheezing is apparent as the child is breathing in, too.

Severe

Wheezing is not apparent because the bronchial tubes are so constricted that they block off the air. As the child's condition gets better, the wheezing becomes apparent again.

Retractions

The area of skin under the rib cage, the soft part of the neck above the breast bone, and the soft tissue over the collarbone *draw in* as the child inhales. This "sucking in" action is called a retraction.



Mild

Retractions are not present.

Moderate

Very mild retractions—if any at all—are noticed.

Severe

Retractions are indicative of a severe attack. In some severe attacks, the skin in between the ribs gets drawn in when the child inhales.

Retractions, whether they are mild or severe, must be reported to your doctor without delay.

A service to physicians and their patients from

Glaxo

children. Careful hand washing and avoidance of contact with infected persons may provide some protection against these asthma triggers.

Virtually all persons with asthma develop symptoms when exercising under certain conditions. Wheezing most often occurs 10 to 20 minutes after exercising. Up to 40% of individuals with allergic rhinitis also have exercise-induced asthma. Avoiding outdoor exercise in cold, dry air may help, but exercise without symptoms is an important treatment goal. Usually a beta agonist drug or cromolyn taken 20 minutes before exercise can prevent exercise-induced asthma.

Between 65% to 85% of older children with asthma have positive skin tests to inhalant allergens especially pollens, animal danders, mold spores, house dust mite, and cockroach allergen. Double-blind, placebo-controlled studies document food allergies in less than 7% of children with asthma.⁴ Occasionally food allergy does provoke wheezing and then the child with asthma requires a special diet. However, it may be a disservice to recommend excessive, prolonged food restrictions based on allergy tests alone if the patient does not develop symptoms upon ingestion of the suspected allergen.

Up to 10% of children with asthma are sensitive to sulfites or salicylates. They need to avoid sulfite preserved foods or aspirin and bismuth subsalicylate (Pepto-Bismol®). Acetaminophen represents a safe alternative for essentially all patients.

Avoidance of inhaled allergens is

essential. Dust mite-sensitive patients who carefully adhere to house dust control measures can decrease their wheezing, their low peak flow rate (PFR), and their need for additional medication requirement from about 30% to about 3% of days.⁵ Special filtration systems to assist in indoor allergen control were reviewed and ranked by *Consumer Reports*, October 1992. Nonspecific irritants that are important triggers include strong odors, perfumes, aerosol sprays, oil-based paint fumes, other aromatic chemicals, and smoke. The presence of tobacco smoke in the home doubles the risk that a child will develop asthma and quadruples the need for medication.⁶ Treatment may be ineffective unless superb environmental control measures are practiced.

Immunotherapy. Immunotherapy (IT) against inhalant allergens has been found effective in about 75% of placebo-controlled studies,⁷ significantly improving symptom-medication scores, pulmonary function, and/or decreasing specific bronchial reactivity. IT using molds is of less certain benefit than with pollens or dust mite allergens.⁸ Molds may require separate injections since their proteolytic enzymes may destroy pollen allergens. IT should be considered for sensitive patients when allergen avoidance is not possible and medication fails to control allergic asthma symptoms.¹

Although systemic reactions may approach 10% during the course of standard IT, deaths are rare, occurring only once in several million injections.⁹ The National Asthma Education Program (NAEP) recommends that IT only be administered in a physician's office with facilities and personnel to treat systemic reactions.¹

Injectable IT with food antigens may be of benefit but carries major risks. The primary treatment of food allergy

is avoidance.¹ The value of using sublingual food drops and provocation-neutralization techniques has not been proven.¹⁰ Food allergy experts do not recommend food IT for routine clinical use.¹¹

Medications

Pharmacotherapy of asthma is based on classification of the patient's asthma as acute or chronic and as mild, moderate, or severe in intensity. Physicians who care for children should be thoroughly familiar with the NAEP protocols (available in reference 1) for treating mild, moderate, and severe chronic asthma and acute asthma exacerbations at home, emergency department or office, and in the hospital.

The following comments are based on my experience and literature review.

Delivery Systems

Metered Dose Inhalers (MDI). Asthma medications are of two basic types: bronchodilators that cause the smooth muscles around airways to relax; and anti-inflammatory agents that decrease inflammation and reduce hyperreactivity of the airways. Inhaled medications give the most rapid results with the fewest side effects but are only effective when administered with proper technique, (Table 2) which requires split-second timing, and up to 90% of patients have poor technique. Frequent review and coaching can help patients with their technique.

Often the use of spacer devices between inhaler and mouth will provide more effective therapy. Aerochambers are generally for more mature children or teenagers and require careful observation to ensure proper technique, but the Aerochamber with Mask can be used by preschool children and infants. The Inspirease bag can be used by most children age four or older. It has the advantage of visual feedback to confirm proper inhalation. The Optihaler may represent a convenient, compact alternative for the teenage patient. In general, spacer devices should be used by all children under

Table 2. Effective metered dose Inhaler technique¹

1. Shake well.
2. Breath in and out slowly and fully.
3. Place in mouth or 1 1/2 to 2 inches outside of mouth.
4. Actuate and start inhaling.
5. Inhale slowly and fully taking three to five seconds.
6. Hold breath for 10 seconds.
7. Exhale slowly.

age eight on MDI therapy, by all patients using inhaled steroids, and whenever direct technique cannot be mastered or maintained. Meticulous adherence to the manufacturer's directions, and frequent reevaluation of spacer technique is essential. As of February 1992, North Carolina Medicaid will reimburse durable medical equipment (DME) suppliers for spacer devices. The code is W4051, and reimbursement is \$20.54.

Compressor-Nebulizers. Compressor-Nebulizer systems provide larger doses of medication over many breaths and generally require 10 to 15 minutes per treatment. They are useful for sicker patients or those unable to use spacers. In general they are an inefficient means of medication delivery, requiring about 12 times as much medication as is given in two puffs of a corresponding MDI. Since compressor-nebulizers deliver potent doses of beta 2-agonists but not of anti-inflammatory agents, it is crucial that parents have written limits for their use. When frequent doses are required to alleviate distress or to treat low peak flow rates, the physician should be consulted concerning systemic steroid therapy. All children age five and older with home nebulizers must use a peak flow meter (PFM) to monitor the need for and response to treatment. North Carolina Medicaid provides reimbursement to DME suppliers for compressor-nebulizer rental. The code is E0570, and the rate is \$22 per month.

Bronchodilators

Beta-Adrenergic Agonists (beta 2-agonists). Adrenalin (epinephrine) was first used to treat asthma in 1903 and remained the treatment of choice for acute episodes until the 1980s. It has excellent bronchodilator (beta 2) effects, but its strong cardiac (beta 1) effects cause rapid heart rate, palpitations, nervousness, and headache. The injections are painful and therefore many children would deny asthma symptoms to avoid going to the doctor. Subcutaneous epinephrine is rec-

ommended by the NAEP only in emergencies where the patient has impaired consciousness or is unable to generate a PFR.¹ Newer, progressively more lung-specific drugs with longer duration of action have become available in the past decade. Low-dose inhaled terbutaline (Brethaire), albuterol (Ventolin, Proventil), and pirbuterol (Maxair) act within 15 seconds and persist for up to four hours with minimal or no side effects. Albuterol is approximately 300 times more beta-2 specific than isoproterenol and 95 times more than metaproterenol. The major danger in its use at home lies in failure to detect deteriorating lung function and therefore in beginning timely anti-inflammatory therapy. Under emergency conditions large doses of albuterol may be safely used with significantly increased bronchodilator response.^{12,13} Indications and doses are found in the NAEP acute treatment protocols (reference 1). Frequent or continuous high-dose nebulized albuterol may result in hypokalemia. Potassium supplementation and cardiac monitoring are recommended for hospitalized patients.

Recent studies suggest that when potent inhaled beta 2-agonists are taken regularly regardless of need they may actually increase bronchial hyperreactivity and worsen asthma control.¹⁴ For this reason patients who are under excellent control on inhalable anti-inflammatory medications should probably use beta-agonists based on symptoms or on a falling PFR.

Theophylline. Caffeine was used as a remedy for asthma in Scotland by 1859. The related methylxanthine, theophylline, was first used to treat asthma in 1938. This drug is available in both short (6-hour duration) and long-acting (12-hour) oral forms but cannot be taken by inhalation. Side effects, which vary greatly between individuals, include gastric irritation, vomiting, nervousness, insomnia, and headache. Periodic measurement of blood levels is essential because toxic levels can cause seizures and even death. The NAEP recommends a therapeutic range of 5 to 15 µg/mL (lower

than the old recommendation of 10 to 20 µg/mL).¹ Significant fever and the concomitant use of certain drugs such as erythromycin, cimetidine, and ciprofloxacin may slow theophylline metabolism resulting in toxic levels. You should reduce the dose by 50% and monitor serum levels under these conditions.

The NAEP treatment protocols list theophylline as an alternative to cromolyn in moderate chronic asthma. It is not recommended for emergency room use since it does improve the results from frequent albuterol nebulizations in this setting.¹ Theophylline is recommended for essentially all in-patients.¹ Theophylline may produce behavioral disturbances in certain children, but the FDA has found no data to support a general adverse effect on the performance of schoolchildren. Theophylline may worsen gastroesophageal reflux, a trigger for asthma in certain patients.

Atropine and Atropine Derivatives. Inhalation of smoke from burning stramonium leaves was used to treat asthma in India in the early 1800s. Subsequently this substance was popular in the U.S. after 1920 as Schiffman's Asthma Cigarettes. Atropine was not widely used because of its side effects (dry mouth, blurred vision, rapid heart rate, urinary retention, and hallucinations). Since 1986 Atrovent (ipratropium bromide), a non-absorbable atropine derivative, has been available as a metered dose inhaler in the U.S. It is a weaker bronchodilator than beta-adrenergic agents and slower in its onset of action (15 minutes). It is useful for patients with mild asthma who are sensitive to beta 2-agonist side effects and for adults with chronic obstructive pulmonary disease. The nebulized form, not available in the U.S., has been shown to increase the bronchodilation provided by nebulized albuterol.¹⁵

Anti-Inflammatory Medications

Cromolyn (Intal). Cromolyn was first derived from khellin, the active principle of the Egyptian plant *Ammi visnaga*, used

since antiquity as a muscle relaxant. It was synthesized in 1965 and approved for use in the U.S. in 1973. A single dose is 1600 µg by MDI or 20 mg by nebulizer. Cromolyn prevents release of chemical mediators of bronchospasm and inflammation from storage granules in mast cells. It has an outstanding safety profile and essentially no side effects or toxicity. This makes cromolyn the first choice as an anti-inflammatory agent for children with chronic moderate asthma. Regular use before exposure to triggers produces its protective effect. It has no significant bronchodilator activity and is therefore not useful in reversing acute bronchospasm. When used with a beta-agonist, the bronchodilator should be taken first. Its use should be continued or increased during asthma exacerbations. Older recommendations to discontinue use were related to the possible bronchospastic effect of the inhaled powder. Most studies show that inhaled steroids are more effective than cromolyn and the combination is no more effective than inhaled steroids alone.¹⁶⁻¹⁸ When adequate doses of inhaled steroids are ensured, cromolyn may be discontinued, allowing significant cost savings and improving compliance by simplifying the drug regimen for those patients.

Inhalable Corticosteroids. Inhalable corticosteroids are potent anti-inflammatory agents with a high ratio of topical to systemic activity. These drugs, available as metered dose inhalers since the 1970s, include beclomethasone (Beclovent, Vancril), triamcinolone (Azmacort), and flunisolide (Aerobid). Flunisolide (250 µg/puff) and triamcinolone acetonide (100 µg/puff) are delivered in larger doses than beclomethasone (42 µg/puff). The potency of beclomethasone dipropionate is up to five times greater than other steroid agents¹⁹ and its topical to systemic selectivity up to twice as great.²⁰ The longer duration of experience with beclomethasone may favor its use. Doses up to 14 µg/kg/day (equivalent to 1 puff/day for every 3 kg of body weight) do not cause adrenal suppression.²⁰ Both BID and QID dosing are

effective. Spacer devices may decrease oral deposition of inhaled steroids by up to 90% thereby decreasing bitter taste and enhancing compliance. When used with spacer devices in proper doses these drugs rarely produce thrush or hoarseness. They are best used in patients with severe chronic asthma or in those with moderate asthma who have inadequate control with cromolyn. Increasing the dose of inhaled steroids during mild asthma exacerbations (detected by measuring PFR) may result in resolution over a period of three to seven days and thus avoid severe deterioration requiring systemic corticosteroids.³ Like cromolyn, use of corticosteroids should be preceded by inhalation of a bronchodilator when bronchospasm is present.

Nebulized inhalable steroids have been used in infants and preschool-age children with severe chronic asthma, but one published study showed no benefit.²¹ At present the best approach might be to deliver a corticosteroid by MDI using an Aerochamber with mask. No nebulizable preparation is available in this country but one (budesonide) is available in Canada. The large doses used in a nebulizer are tolerable with budesonide because it has very little systemic effect. The use of nebulized nasal flunisolide solution (Nasalide) as treatment for asthma is not approved by the FDA, and no controlled studies have proven its efficacy in this regard. There are concerns about possible growth suppression from inhaled steroids, but uncontrolled severe chronic asthma itself may cause growth failure and is life threatening.

Systemic Corticosteroids. Cortisone became available for the treatment of asthma in 1948 and was dramatically effective. Patients who had always wheezed became wheeze-free and mortality rates fell. It was soon learned, however, that prolonged administration over a period of many months led to the serious side effects of hypercorticism: truncal obesity, weak bones, cataracts, and diabetes. There followed a steroid phobia among patients and physicians that is only now resolving. It seems clear

that short courses (less than two weeks) of corticosteroids administered infrequently (less than four times per year) are relatively safe and free of side effects. Short-term effects may include increased appetite, flushed cheeks, and occasionally muscle and skin tenderness. Patients who experience swelling associated with prednisone and prednisolone may tolerate methylprednisolone, which has one half as much mineralocorticoid effect or from dexamethasone, which has no mineralocorticoid effect, but a long biologic half life (36 to 54 hours) that makes it inappropriate for alternate day therapy.

A recently recognized hazard of systemic steroids is the potential to make chicken pox more severe or potentially fatal.²² The varicella-susceptible asthma patient requiring systemic corticosteroids should be cautioned about exposure to varicella or zoster before and during therapy. Varicella zoster immune globulin and acyclovir should be used and infectious disease consultation obtained as needed for exposed patients.

Remember that systemic corticosteroids are the only medications that reverse moderate to severe airway wall edema and mucus production. They also create new beta-agonist receptor sites. They clearly can be life saving and should not be withheld when indicated. Early, short courses may avoid late, longer courses with higher total exposure.²³

Antihistamines

Antihistamines are not primary agents in asthma management, but patients may benefit when they provide improved control of associated allergic rhinitis. The American Academy of Allergy and Immunology requested in September 1988 that the FDA stop labeling antihistamines as contradicted in asthma unless an adverse reaction has been previously demonstrated. Recent studies have shown mild bronchodilator effects and protection against exercise-induced bronchospasm especially with the newer non-sedating antihistamines.²⁴ Maintaining a patent nasal airway (even by adding oral decon-

gestants and nasal steroids) allows proper filtration, warming, and humidification of inspired air. An additional benefit of controlling allergic rhinitis may be a reduction in sinusitis, an important trigger for asthma exacerbations.

Peak Flow Monitoring

The peak flow meter is to asthma as the thermometer is to fever. It provides an objective measure of lung function and can be used to detect asthma triggers. It can identify early asthma exacerbations before symptoms are obvious. Peak flow rates serve as a guide to medication type, dose, and frequency. They can help the patient avoid under- and overdosing. They can reassure the apprehensive patient and parent or can provide life-saving information by activating an emergency management plan.

The NAEP recommends measurement of peak flow rates twice a day in all children age five and older who have at least moderate asthma.¹ I recommend the "Stop Light" approach (Table 3), originally described by Mendoza²⁵ and Plaut.²⁶ All patients with moderate or worse chronic asthma should have a peak flow meter and follow a written Peak Flow-

Based Asthma Management Plan (PFBAMP). The patient's brand and range PFM should be recorded on the PFBAMP. Comparable meters should be available at the office and hospital, and the patient should bring his or her own meter to medical visits.

Peak flow meters have been available under the state Medicaid Program since 1991. (Types of peak flow meters on the market are listed in Appendix B.) A prior approval form is required. The HCPC code is W4043 and reimbursement is \$28. As with spacers and nebulizers, physicians' offices may apply for DME supplier certification and supply these products directly to their patients. This requires a separate DME supplier number distinct from the physician's service provider number.

Generally, low-range meters are best for children age four to eight and full-range meters for children age eight and older. The low range Mini-Wright registers values about 40 points lower than the full-range model. The Pocket Wright tends to read higher than the Mini-Wright, while the Assess tends to read lower. A study of the relative accuracy and reproducibility of eight different PFM brands is available.²⁷

Asthma at School

Asthma is responsible for more school absences than any other chronic condition in childhood, but much remains to be accomplished in educating school personnel about asthma management. Environmental control can be improved if teachers insist on dust- and mold-free heating systems and classrooms. Windows should be kept closed even on temperate fall and spring days. Warm-blooded pets and non-specific irritants should not be allowed in class. Classrooms for chemistry, art, and shop must be well-ventilated. Schools should be painted with latex paint during vacation months. No students should smoke.

The American Academy of Allergy and Immunology requested in 1989 that schools cooperate by permitting the students to have possession of their inhaled medications. These drugs have no potential for abuse by other students. Forms developed by the American College of Allergists and endorsed by the American Academy of Pediatrics for communicating with teachers, coaches, and nurses are excellent and available through ALANC. Valuable references for school systems are listed in Appendix C.

Establishing effective asthma management programs in North Carolina's public schools will require the provision of peak flow meters and the expertise to use them. Elementary schools will require both low- and full-range meters, while full-range meters alone should suffice for upper-level schools.

Several steps toward improved school care for children with asthma are already underway. Mini-Wright meters will be provided through a grant from Schering to all public schools in Wayne County by second semester of the current school year. In September 1991, the executive committees of the North Carolina Pediatric Society and ALANC agreed to work together to facilitate the adoption of the NAEP school asthma management strategies. Dr. David J. Henderson of Reidsville and the North Carolina Pediatric Society School Health Committee have developed the Teaching Enhanced

Table 3. Peak flow-based asthma management plan*

- **Green Zone:** (Pre-medication PFR 80% to 100% of personal best). Continue maintenance therapy, if any. Use bronchodilators to treat symptoms or before using anti-inflammatory agents if directed.
- **Yellow Zone:** (Pre-medication PFR 50% to 80% of personal best) Caution zone! Increase bronchodilators and anti-inflammatory medications. Many experts divide this zone in half, doubling or tripling inhalable corticosteroids in the high yellow zone (PFR 65% to 80%) until all PFR are in the green zone for two days. Nebulizations and systemic corticosteroids are generally required in the low yellow zone (PFR 50% to 65%).
- **Red Zone:** (Post medication PFR <50% of personal best). Danger zone! Needs prompt immediate communication with the physician and activation of personal emergency plan, which may include markedly increased beta agonist dosing and immediate systemic corticosteroids according to NAEP protocols. Significant carbon dioxide retention correlates with PFR less than 25% of predicted in adults.

*Guidelines based on the author's experience

Asthma Management Skills (TEAMS) program that holds great promise for statewide application. The North Carolina Thoracic Society and ALANC are forming a joint Asthma Committee to review

current programs in asthma education and to recommend objectives and strategies for reducing morbidity and mortality from asthma in the state. Physicians interested in assisting in the development

and implementation of such programs should contact the author through ALANC. □

Appendices

Appendix A. Resources for patient education

The following resources for patient education are highly recommended:

1. Allen and Hanbury's Respiratory Institute, Five Moore Drive, Research Triangle Park 27709. Publications include:

- *Assessing the Symptoms and Severity of an Asthma Attack* (Plaut). This guide is out of print but may be photocopied from this article. Permission granted by Dr. Plaut and Allen and Hanbury's.
- *I'm a Meter Reader* (Sanders). Video also available.
- *A Patient's Guide to Asthma* (Leffert)
- *So You Have Asthma Too* (Sanders). Video also available.

Videotapes include:

- "A Patient's Guide to Peak Flow Monitoring"
- "Ventolin Rotahaler" (technique)
- "What Americans Should Know About Asthma" (Kaliner)

2. American Lung Association of North Carolina, Central Office, 916 W. Morgan St., Raleigh 27611. 919/832-8326.

Resources include:

- Family Asthma Saturday Programs—Whole or half-day instruction for patients and parents. Contact your regional ALANC office for scheduled programs or help in organizing your own.
- Camp Challenge—The state's only asthma camp—see accompanying article on next two pages. Many partial and full camperships are available. Applications and videotape available from Camp Challenge, P.O. Box 6176, Raleigh 27628; 919/782-2888, or your regional ALANC office.
- Published materials and videotapes—"Effective Use of Inhalable Medications in the Management of Asthma." 40-minute video available, 1991. Contact ALANC for other currently available titles.

3. Mothers of Asthmatics, Inc., 10875 Main St., Suite 210, Fairfax, VA 22030; 703/385-4403. Publishes a monthly newsletter. All the Sanders books and videotapes are available, and peak flow meters may be ordered. Membership is \$25 per year.

4. Pedipress, Inc., 125 Red Gate Lane, Amherst, MA 01002. Publications by Thomas Plaut, MD, including:

- *Children With Asthma: A Manual For Parents* (300 pages).
- *One Minute Asthma* (32 pages). A limited number are available at no charge from Fisons.

5. Scherling Corporation. Videotapes include:

- "Inhaler Techniques and Inhaler Maintenance" (featuring Christopher Reeve).
- "Running Hard, Breathing Easy: The Jeanette Bolden Story."

Appendix B. Peak flow meters are available as follows:

1. Mini-Wright Peak Flow Meters

Full Range PF-239 (0-800 L/min)
Low Range PF-240 (0-370 L/min)

Quantity discounts, \$18 to \$28. From Armstrong Industries, 1-800/323-4220; or Clement Clarke, 1-800/848-8923.

2. Pocket Wright Peak Flow Meters

Standard (75-800 L/min)
Low Range (50-450 L/min)

From Market Technologies, \$21 each.
1-800/768-5842.

3. Assess Peak Flow Meters

Standard (60-880 L/min)
Low Range (30-390 L/min)

From Healthscan for \$19.95 each.
1-800/962-1266.

Appendix C. Valuable references for school systems

1. Asthma in The School, Improving Control With Peak Flow Monitoring, by Guillermo Mendoza, M.D., 80 pages. Published by Healthscan in 1989 and available through Allen and Hanbury's or Mothers of Asthmatics (addresses above). This is a complex plan requiring great effort and organization.

2. Managing Asthma: A Guide For Schools. From the National Asthma Education Program. 17 pages plus reproducible "asthma action sheets" for specific school personnel. September 1991. NIH Publication #91-2650. The basis for school asthma management. A slide program will be available through ALANC for physicians to use in presenting this program to schools and principal meetings.

3. Open Airways for Schools. Developed by Columbia University and the American Lung Association. Endorsed by the NAEP. Designed to identify and educate children with asthma in grades three through five. Available January 1993.

Camp Challenge: A Summer Camp For North Carolina Youths with Asthma

by Rubin F. Maness, M.D.

The benefits of asthma camps include increased self esteem, self reliance, and confidence among campers.¹ Interpersonal and family relationships also improve as well as overall social adjustment. Since depression is a significant risk factor for asthma fatalities, these benefits, in addition to asthma management education, mean that the camping experience may be life saving.² I review here the nine-year development of one such camp.

Camp Oak Hill and Retreat Center, located 16 miles north of Oxford in Granville County, is the site of North Carolina's only asthma camp, Camp Challenge. Since its beginning in 1984, camp enrollment has grown by more than four fold. Camp facilities, organization, staffing, supplies, and camper educational programs have kept pace with increasing camper enrollment as well as with national and international advances in asthma management.

The Background

Oak Hill School was built in 1924 to educate children from grades one through 12. Gregory Poole, Sr., was the president of the first graduating class of 16 students. In 1960 a tornado struck the school, demolishing its rear wing, and subsequently the school fell into disuse. In 1970 Gregory Poole, Jr., and a group of area businessmen, purchased the school and grounds in order to establish a non-profit, non-denominational Christian camp. Max H. Cooke became the first executive director for the camp and, in the summer of 1977, 33 children attended the first session of Camp Oak Hill.

The 17-acre site has undergone major improvements over the years, including the construction of the 250-seat Irene Poole Dining Hall in 1982, and of four modern duplex cabins housing 14 campers and two counselors per side in 1986. In 1987 the 25-meter Robert Logan, Sr., Memorial Swimming Pool was constructed to supplement the aquatic facilities provided by a 3-acre lake. Current enrollment at Camp Oak Hill now exceeds 600 campers per summer. Activities include archery, basketball, canoeing, fishing, field sports, horseback riding, rappelling, nature walks, riflery, swimming, and tennis. All activities are led by qualified instructors with an emphasis on safety, skill development, relationship building, and participation by all. Christian values and ideals are presented in an atmosphere of understanding and acceptance of other beliefs. The staff to camper ratio is 1:4.

Camp Challenge

In 1984 Dr. James Poole, a second generation Raleigh pediatrician, founded Camp Challenge. Dr. Poole, a board member of Camp Oak Hill, understood the special needs of youth with asthma since he himself had suffered from asthma during childhood. Medical leadership was also provided by

Dr. Craig F. Laforce, director of pediatric allergy at the University of North Carolina at Chapel Hill. The Downtown Raleigh Rotary Club provided seed money and, in 1984, 24 campers attended the first session of Camp Challenge. By 1987 enrollment increased to 63, and the camp was officially endorsed by the American Lung Association of North Carolina (ALANC).

The ALANC Asthma Camp Committee was chaired initially by Dr. George Wolfe, later by Dr. William Hopper, and presently by Dr. Al Driver. In 1987 Dr. Rubin F. Maness, a Goldsboro pediatrician and state ALANC Board member, began service as a camp physician and subsequently as co-medical director with Drs. Poole and LaForce. Deborah M. Williams, RN, is head nurse and provides essential leadership in recruiting and scheduling nurses, respiratory therapists, and other volunteers. Mary S. Maness, R.Ph., serves as Camp pharmacist and assists in camper education. A physician certified in Pediatric Advanced Life Support is on the premises at all times. The ratio of staff to campers suggested by ALANC (1:15) is always met and usually exceeded. Enrollment totaled 106 children with asthma in 1991, and 98 in 1992.

The Camping Routine

The camp is equipped with an extensive array of supplies to handle both routine medical problems and asthma. This includes intravenous fluid equipment, oxygen tanks, airway resuscitation kits with laryngoscopes, endotracheal tubes, bag and masks, battery operated nebulizers, and an emergency IV medication kit. Recent equipment additions include an oxygen concentrator, pulse oximeter, and a 4,000-watt generator in case of electrical outages.

All campers report to the health room three times a day. Baseline peak flow rates (PFR) are obtained on arrival at the camp; peak flow rates are also measured each morning and evening before and after



A young camper blows into a peak flow meter at Camp Challenge.

medication is taken and the values obtained are plotted according to height. Peak flow rates are ranked according to the recommendations of the National Asthma Education Program (Green Zone = 80% to 100% of predicted PFR; Yellow Zone = 50% to 80% of predicted; Red Zone < 50% of predicted).³ All campers with PFR in the Yellow Zone are examined by the camp physician who makes any indicated change in therapy. Any camper in acute distress is always seen by the physician, and no camper with PFR in the Red Zone is allowed to leave the health room.

All treatment follows the protocols for treatment of children with acute asthma established by the NIH Expert Panel on Asthma in the National Asthma Education Program, 1991. We also have emergency transport protocols, but no camper has had to leave camp due to asthma. We have been able to achieve improvements in pulmonary function (Figure 1) largely by modifying drug doses or by ensuring proper technique with metered dose inhalers and spacers (see accompanying article, page 636). Fewer than 10 campers have needed systemic corticosteroids during the past two camp sessions combined. No camper has ever needed treatment with epinephrine while at camp.

Camper education currently consists of classes held Monday through Thursday mornings on the following topics: Introduction to Asthma; Asthma Triggers; Asthma Medica-

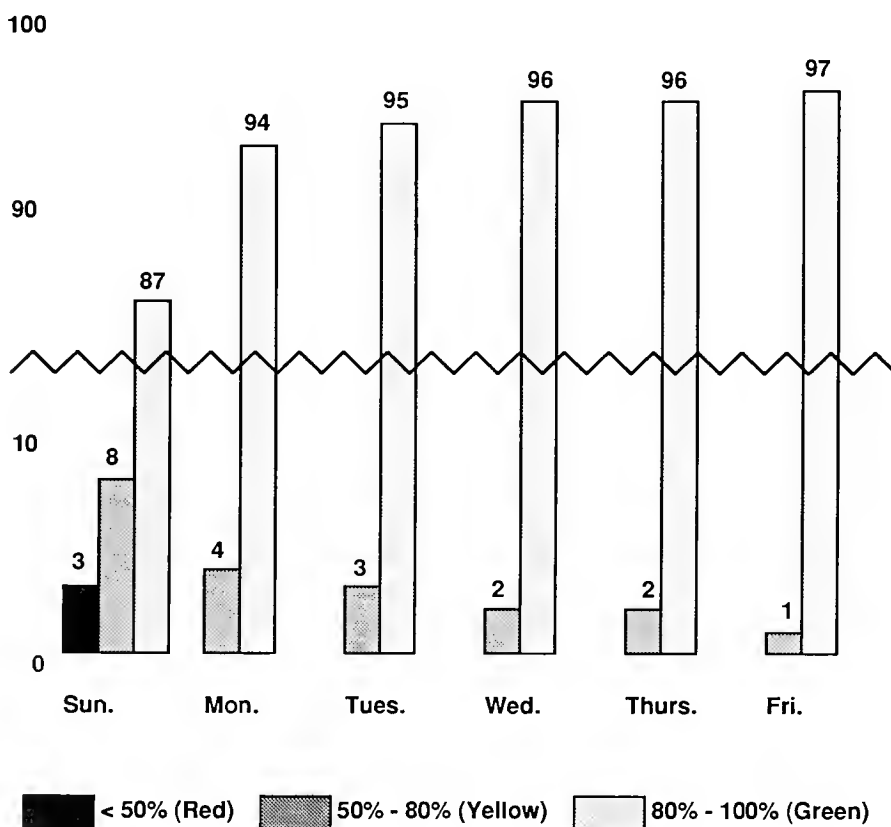
tions; Effective Use of Metered Dose Inhalers and Spacers; Peak Flow Meters; Asthma Management Plans; and the final session, What Asthmatics Can Do. The potential for all asthmatics to control their asthma and to excel in life is emphasized. Visits by world-class athletes with asthma such as Cheryl Decker and Bob Gibson bring these points home. Written educational materials are provided to the campers and their parents. During the past five years peak flow meters have been provided for all campers to take home.

Camp Challenge, now in its ninth year, fulfills a vital role in the care and education of children with asthma in our state. The camp is now near maximum capacity and the medical directors are eager to assist other areas of the state in developing regional camps (Virginia presently has six asthma camps⁴). Since there is a rising prevalence, morbidity, and mortality of asthma, and since we are now equipped with NIH-endorsed techniques that are documented to control the disease, we encourage interested physicians to establish additional camps in North Carolina. ALANC, Dr. David Brown, and Dr. Don Russell will establish Camp Mountain Air, serving 40 campers in the Asheville area, August 8-14, 1993.

Camp Challenge fulfills the guidelines for the Operation of Camps for Children with Asthma developed by The Consortium on Children's Asthma Camps in 1992. Camp Challenge accepts campers with asthma aged 8 to 14 years,

regardless of race, color, religion, or national origin. Eighty-five percent of campers attend on partial or full camperships funded by Camp Oak Hill, ALANC, and private donations. □

Figure 1. 1992—Distribution of peak flow rates during one week at Camp Challenge



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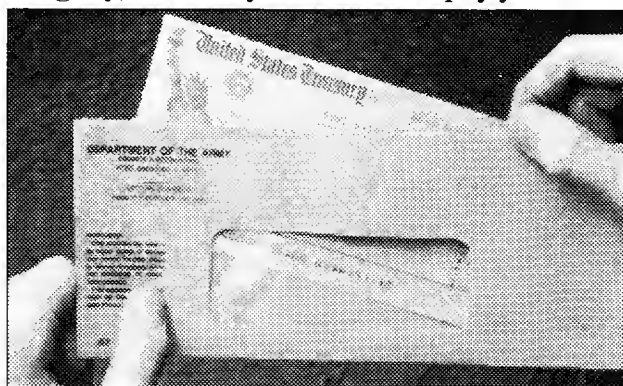
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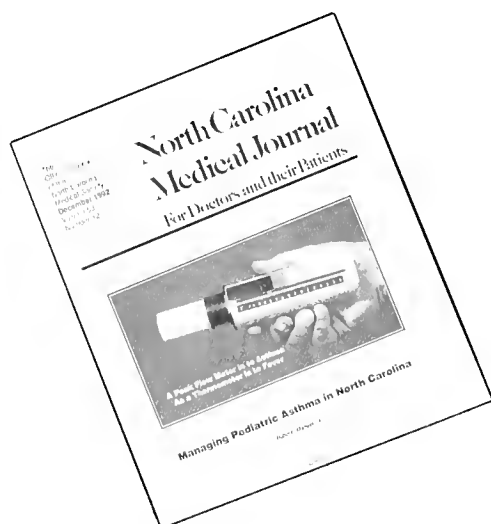
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FEATURE FOR PATIENTS

NORTH CAROLINA MEDICAL JOURNAL
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They Wrote Us a Poem

By Kate Daniels

The last place one might expect to find poetry is in a state-of-the-art, 900-bed, tertiary care medical center like the one at Duke University. Death-defying medical interventions, seemingly miraculous cures, and the dazzling apparatus of post-modern medical technology—these are what characterize such a place, along with emotionally overloaded staff members, administrators obsessed with managing the costs of hospital care, and desperate patients reckoning their chances of survival. The unrelenting atmosphere of crisis that permeates most medical centers seems to preclude the silence and solitude that are necessary for the creation and appreciation of poetry. It seems paradoxical that now, when the body's immediate needs are tended to with greater success than at any other time in history, the soul suffers silently. I mean this not only with regard to patients, but for employees and medical staff, too, who work under the most emotionally stressful of conditions, day in and day out. The costs of everything else are carefully calculated in hospitals today, but the human costs of psychic survival in such an atmosphere are rarely considered.

It was the need to address the high emotional and spiritual costs of working in a modern medical center that led to the formation of a remarkable group at Duke University Medical Center in 1988. Initially led by DUMC's poet in residence Grey Brown (and later, Cedar Koons), employees, doctors, students, and friends from all over the hospital began meeting weekly to read and discuss contemporary literature. Participants often brought their lunches and ate them around a conference table while talking about short stories, novels, and poems by such writers as Reynolds Price, Ellen Gilchrist, and Lee Smith. The only criteria for readings have been that the

work be good and able to be discussed within one or two sessions. Like everyone else who works in a medical center, the participants have little free time and only minimal control over their hours in the workplace. Stealing this one hour each week does not automatically guarantee them the right to relax uninterrupted. Beepers go off at each meeting, and someone inevitably jumps up and leaves to answer a page.

Over the years, the group has developed far beyond the model of the literary lunch that it took for itself at the beginning. Initially calling themselves, "I Want to Read You a Poem" and "Stellar Stories," the group is now known as the Osler Literary Roundtable, in honor of Sir William Osler who advocated the cultivation of the arts and humanities in physician training and practice. Besides discussions of poetry and fiction, the roundtable sponsors readings by visiting writers and various kinds of special projects, as well as acting in an advisory capacity to the poet in residence who leads the group.

The benefits of the group have been enormous for those who participate, providing a place to communicate across conventional boundaries and to bring their very ragged human feelings to rest and recuperate. Tucked back in a corner of the offices of the dean of the School of Medicine, each meeting convenes with a ritualistic round of introductions, which includes the department or division of the medical center that each participant represents. Pharmacology, Neurology, Psychiatry, Pastoral Services, Medicine, Surgery, Pediatrics, the Eye Center—they come from all over the hospital. By the time the naming is concluded, the tension level in the room is already lower. For the next hour at least, one can rest off guard, free to feel or say whatever one wants. No human feeling here is taboo. The perpetually on-guard atmosphere of a medical center, where the most basic and inevitable of human emotions must often be suppressed in order to get the job done is—for

Ms. Daniels is the Poet In Residence, Cultural Services, Duke University Medical Center, Durham 27710.

awhile at least—suspended. The atmosphere is remarkably relaxed, and while no one at the roundtable may be cured—the major work of the hospital—certainly everyone who participates is healed in some way that is vitally important to emotional health and spiritual well-being.

In the spring of 1992, the Osler Literary Roundtable decided to sponsor a poetry contest for the entire DUMC community. If the 20 to 30 people who come to the roundtable each week felt such a strong need for creative expression through the literary arts, the group reasoned, might there not be such a need among the hospital population at large? And so, "Write Us a Poem" was born. Sponsored by Cultural Services, the contest was advertised throughout the medical center and city of Durham. The contest was open to "any person having ties to Duke University Medical Center, including former and present staff, employees, volunteers, patients, and their immediate family members." Poems could not exceed 75 lines, and were to address themselves to "the themes of the practice of medicine and other health professions, compassionate care, death and dying, the experience of illness, pain and suffering, and the healing process."

In all, 87 entries made their way to the offices of Cultural Services by the June 30 deadline. The poems were shipped off to the judge, poet Richard Kenney of Seattle, Washington, a MacArthur fellow and author of two award-winning volumes of poetry, and then the roundtable began two months of reading and discussing the poems that had been submitted. Immediately, it became clear that the call for poems from the DUMC community had touched a real need among employees, patients, and their families. The poems overwhelmed us with their deeply felt expressions of emotion. Voices that usually seem silent in the vast workplace of the hospital spoke up: grieving relatives, nurses' aides, clerical workers. And many voices that we were accustomed to hearing changed their tenor: the emotionless self-control of doctors gave way to deep feelings about the patients they treat, and the patients, so often seen as passive and victimized, raised their voices in both praise and protest. All of a sudden, the invisible side of life at DUMC came to light; from laughter in the midst of tragedy...

Ten Things to Do While Having a Heart Attack

Relax.

(Panic depletes your oxygen supply.)

Remember life or its lack
cannot be taken personally
or too seriously.

Think how surprised all the people
who accused you of not having one
are going to be.

Call up your happiest memory
whether a desert sunset of shimmering turquoise skies
shot through with flickers of scorched gold
or how much you gypped the IRS out of.

Tell the Rescue Squad how angelic
they look even without wings.

Be glad you have on
clean underwear.

Congratulate yourself
on convincing the Life Flight helicopter pilot
not to cut your Nikita Koloff tee-shirt off.

Wish you had paid closer attention
when the American Heart Association
began preaching the cholesterol gospel.

Arrange for a sibling
to feed your Siamese cats
and to call your supervisor at work
conveying profound regrets
for unavoidable nonattendance.

Pray.

—By Virginia Love Long, of Hurdle Mills,
a former DUMC patient.

...to tears in the midst of stoicism...

The Land of the Living

I water your plant every week
and remember you
in the land of the living

I remember you questioning
where our souls pass on to
when we're no longer
in the land of the living

Your tiny hands and laughing eyes
shine out to me from children's faces
I pass in the land of the living

I always remember the sweet hearts
and gentle acts
we all perform when patients near death's door
But oh my soul aches to see
if we could do them so much more
when we walk daily through
the land of the living

—By Debbie Pakes, of Durham,
a recreational therapist at DUMC.

...to the deep compassion that so often underlies the veneer of clinical coldness...

Hospital Chaplain

When he first saw Anne,
Surreal beneath the dim and haze
Of life-support equipment,
The lines and tubes in tangles, diving into skin,
Like endless ropes and buoys thrown to reach her;
Her mottled arms and legs
Still now, acquiescent,
and her morphine-lidded gaze
Regarding without questioning—
He stood and pressed the wall,
A witness to her drop by drop drowning,
Then moved toward her with arms
Intent to hold, intent to save
Numb limbs that slipped too easily from him,
Lost to the thick salt-heavy waves.

The waves beat against his brow and cheeks for years
Inside these rooms
And etched deep grooves—their gift to him;
They made his face a living sculpture
Of compassion.

—By Carol Baker, of Durham,
a second-year Duke medical student.

...these poems announced over and over that regardless of how dehumanized and over-technologicalized our modern medical centers may seem to be they are ultimately the most human places of all—never more than a function of the patient served and the staff who serve them.

What follows are the three poems that won first, second, and third prize in "Write Us A Poem." The choice of any is, in a way, arbitrary, for the best thing to do would be to publish all 87 poems in order to give an idea of the range of the poems we received, the variety of topics and styles, and the astounding diversity of the people who wrote them. Barring that, however, let these three stand for all 87, representing the indomitable will of the human spirit to survive even the most saddened and stressful of environments. And let those who read these poems remember the next time they enter a medical center as patient, visitor, or staff, that at the heart of the establishment beats something other than the hum of machinery—these very human voices murmuring comfortingly, sometimes singing, and always reminding us of our own humanity, and that of others. □

First Place

Grocery Store, Years After Your Father's Death

You see the way the knees turn out in mid-step.
the head in profile, skin slightly chalky after shaving.
And always the hat. Crushed by his hands,
that old tweed thing is set just so.
Someone should've warned you
that longing can take shape, that anyone can wish
for a certain blossom to appear in a thicket,
even out of season, and the imagining will draw it out—
a ragged robin high on an Alpine slope,
why not your father, years after
you slipped the ring from his finger,
dark veins of the insignia still warm.

Your father here, now, morning of the first frost.
You walk over to him, grab your own hand
to keep from pulling his around you
as if you were going to dance. And then you say
to this man who offered, perhaps,
to pick apples for his wife,
this man who happens to have lips, skin,
hair, a face, a shape you will look for everywhere
the rest of your life, you say to this sudden stranger
in that single-minded way of yours,
I've been expecting you.

—By Judy Goldman, of Charlotte, a reader at DUMC.

Second Place

I Try to Tell Her

Go ahead and die now, why don't you?
God knows I love you
but I can't take much more than this
waking in the middle of the night to you
walking around in my head
as if you owned the place.

Like the other night when you said—
Come into the woods, I need to die
and I just can't get it right.
I'm your friend so I didn't question
though I felt embarrassed.
When you're dead, you should know you're dead
especially when everyone else does.

You said, Now cover me up with leaves
and then we'll sit real still
until I die. I did and we sat
and we waited. 'Till finally
you kicked up, arms flying out
saying, This ain't the way.

We gotta go back to the house, you said,
go upstairs, pack it up.
Gotta get things ready
before you go.

We packed your cherry red Samsonite,
your overnight bag and stuffed your cosmetic case.
We packed your favorite things,
the worn jeans, blue mascara,
Look Homeward Angel and a good radio.
And we waited.

We waited for someone to climb the stairs
to take you. I sat on the bed
propped against the wall.
You laid your head in my lap and slept.
I could not wake you to tell you
that no one was coming. I could not be the one
to say, Get up, get going,
you've got to leave on your own.

—By Grey Brown, of Rocky Mount,
former poet in residence at DUMC.

Third Place

Quality of Pain

Let us praise the blind and wakeful watchman, Pain:
How startling his clarity of voice,
Like the horn before the hunt;
How valiant and resourceful a fighter,
Like doomed Hector;
How varied and arresting his devices—
The coffeewarm rumble of oceangrey cramps;
The shrillthrill limebite of a copperpoint sting;
The cinnamon red panic of a jarred head;
A bullet wound's minty blue thunder;
The black and white glass elegance of a cancer mosaic;
And the candy-pink humor of an itch.

Let us praise the despised companion, Pain,
For fear that he will cease, discouraged;
For fear that he will slide back the bolt,
Walk out, and float himself to sleep
On the waters of Lethe, leaving the gates unguarded
Against the charming thief, Death.

—By G. Kay Bishop, of Durham, senior data technician,
Division of Social and Community Psychiatry, DUMC.

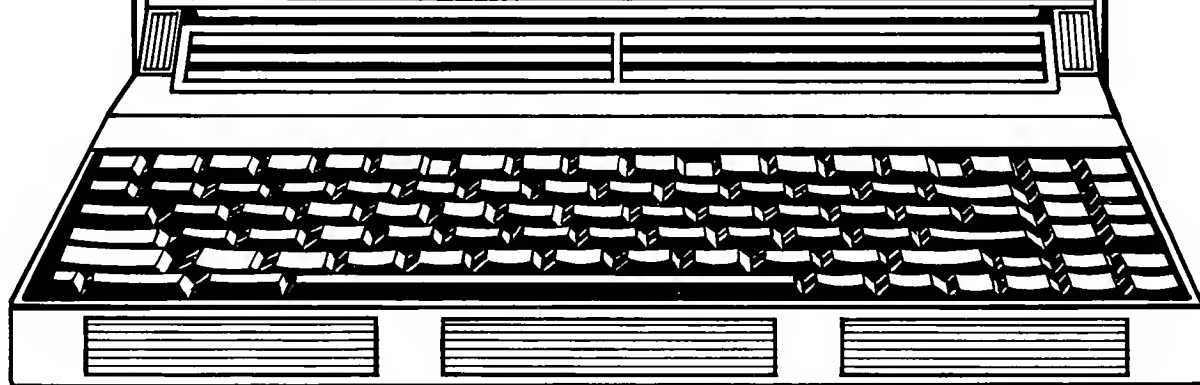
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Risks, Reactions, Regulations, and Reality

Health Care Workers with HIV Infection

Daniel J. Sexton, M.D.

Controversy continues to swirl around the issues of health care workers and human immunodeficiency virus (HIV) infection. Much of the public and many health care workers themselves presume that, because HIV infection is fatal, *every* measure designed to limit its transmission is justifiable—even those measures that are expensive or of marginal benefit. If opinion polls are accurate, the vast majority of Americans believe that *all* physicians should have serologic testing for HIV and that HIV-infected surgeons should be prohibited from practicing.¹ Such opinions seem intuitively logical and right to many educated and well-meaning people. However, there is another side to this issue. Most infectious disease experts argue that such restrictions are not necessary. Who is right? What is the best policy? A review of the data available regarding risks of occupational HIV transmission is a useful starting point for examining these questions.

Currently as many as 11,500 nurses, 5,800 physicians, 1,400 dentists, and 400 surgeons in the United States are HIV-infected.² At first glance these numbers appear alarming—were these people infected through work-related exposures? It is important to note that more than 6.5 million people work in the U.S. health care system,³ and that the rate of HIV infection in health care workers is actu-

ally *lower* than in the general U.S. population. Furthermore, at least 94% of health care workers with AIDS have a nonoccupational risk factor (such as homosexuality or bisexuality) that probably explains how they acquired the infection.⁴

The risk of transmission of HIV from patients to health care workers has been assessed in surveys and by numerous surveillance and follow-up studies.⁵⁻⁸ During this first decade of the HIV epidemic a total of 32 well-documented instances of occupational transmission and 69 additional cases of possible occupational transmission have been noted.⁵ Each of these cases is a personal calamity, but they allow us to calculate that the overall risk for health care workers is small, given the huge size of the denominator (6.5 million) and the duration of surveillance (more than 10 years). Thus the annual risk that an individual health care worker will acquire HIV infection through occupational exposure is very small—less than 2 per million per year (i.e. 101 cases in more than 60 million person-years of exposure).

Low as the risk is that health care workers will be infected by exposure to patients, available data suggest that the risk of transmission of HIV from infected health care workers to patients is even lower. In fact this risk may be lower than the risk of some everyday activities: The risk of dying in an automobile accident in the U.S. is approximately 240 per million per year (0.6/million/day or 4/million/week); the risk of fatal electrocution from home wiring or home appliances is 1 per

million/year.⁹ Most Americans accept such risks as “normal” and go about their daily tasks without emotional or intellectual difficulty. It may help to know that the risk of a patient acquiring HIV from an HIV-infected health care workers is substantially lower than the risk of driving a car to and from work for a week. The chance that a patient will become infected during a one-hour operation by an untested surgeon ranges from 1 in 13 million to 1 in 130 million hours of surgery!⁷ The risk of transmission of HIV during surgery done by a surgeon known to be HIV-infected is estimated at 1/42,000 to 1/420,000.

Many infectious diseases specialists believe that these estimates actually *overstate* the real risk. The Centers for Disease Control (CDC) has performed look-back studies on more than 15,000 patients who had invasive diagnostic or therapeutic procedures performed by HIV-infected health care workers, and none have seroconverted as a result of this exposure. These findings have been overshadowed by a single, highly publicized case. A dentist in Florida appears to have infected five patients in his practice. No conclusive explanation for this transmission has been found despite exhaustive investigation.¹⁰ However, circumstantial evidence suggests that standard infection control guidelines were not followed. The dentist had Kaposi's sarcoma and received dental care in his own practice; the handpiece he used may have been contaminated and provided a vehicle for serial transmission between patients

From the Division of Infectious Diseases, Box 3605, Duke University Medical Center, Durham 27710.

since, at the time this outbreak occurred, such devices were not ordinarily sterilized between patients. The consensus opinion among infectious disease and public health experts in the United States is that this isolated incident was an aberration and that, when standard infection control practices are followed, the risk of transmission of HIV from health care workers to patients is almost immeasurably small.² Indeed, if the dentist's office outbreak occurred via instrument-to-patient transmission, this outbreak is irrelevant for current surgical practice in the U.S. Unfortunately, these conclusions came far after this incident was given prominent coverage in the press and television news. As a result there has been a cacophony of voices demanding regulations and laws to limit the practices and work of HIV-infected health care workers.

In October 1991, Congress approved a bill requiring states to adopt the CDC guidelines concerning HIV-infected health care workers or promulgate their own guidelines. In response to this, the North Carolina State Department of Health has promulgated regulations requiring HIV-infected health care workers who perform or assist in invasive surgical procedures, vaginal deliveries, or dental surgery to inform the state health director of their infected status. The director will appoint an ad hoc committee of experts to review each case and decide whether the worker's practice should be limited or forbidden. The Infectious Diseases Society of America strongly disagrees with the need for such reviews. Other specialty societies and the National Commission on AIDS have voiced a similar opinion.

Few activities can be undertaken with zero risk. Many people logically make a distinction between risk they undertake voluntarily (e.g. driving a car or flying in an airplane) from risks they incur involuntarily (e.g. risk from a nuclear power accident).¹¹ Also the risk of dying in an automobile accident is in part reduced by careful driving habits and using seat restraints. But even after making allowances for such measures, driving a car has a measurable daily risk. When put in perspective, the risk of occupational transmission of HIV from health care workers to patients is seen to be less than

“When put in perspective, the risk of occupational transmission of HIV from health care workers to patients is seen to be less than the risk the patient has in driving a car to and from the hospital.”

the risk the patient has in driving a car to and from the hospital or of being electrocuted in their home. The risk of occupational transmission from patients to health care workers is clearly higher than transmission in the other direction, but when the large size of the denominator (the number of health care workers in the U.S.) and the much smaller size of the

numerator (the number of health care workers with known or suspected occupational acquisition of infection) is considered and after the effectiveness of simple control measures such as universal precautions are added to the equation, the risk is clearly tiny.

It is impossible to prove that any given activity has no risk or to quantitate accurately the degree of risk in activities where the risk is extremely low. Further studies to verify and better quantitate the known low risk of occupational transmission of HIV are currently underway. However, such additional data are unlikely to demonstrate that there is absolutely no risk. Nor are we likely ever to be able to design an occupational environment for patients or health care workers that is totally risk free. Regulations and rules that restrict activities of HIV-infected health care workers will have to balance the cost with the statistical risk of transmission. It has been estimated that a proposed program of HIV screening of surgeons and patients in Maryland would prevent one case of HIV infection every 25 to 250 years and would cost \$440 million to \$4.4 billion per case prevented.²

We may never achieve a complete agreement between the public and the medical profession concerning this issue. However, if the parties arguing about the matter could at least agree that the risk of occupational transmission is indeed very small, they could then focus on the real problems: What prevention measures are reasonable and practical? How much are we willing to spend to achieve our goals? □

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The Ministry of Caring

Margot Hover, D. Min.

"Sometimes caregiving 'ain't all it's cracked up to be.' "

Editor's Note: The following commentary is excerpted from *Caring For Yourself When Caring For Others* by Margot Hover, D. Min., to be published by Twenty-Third Publications, Mystic, CT 06355, in spring 1993. Dr. Hover is chaplain and pastoral educator in Pastoral Services at the Duke University Medical Center in Durham. This is the first of three installments that we feel will offer our readers a unique perspective on the many facets of caregiving.

Thomas Merton wrote, "Prayer and love are really learned in the hour when prayer becomes impossible and your heart turns to stone." Caregivers know many of those moments. There comes a time when the old truism, "It's good to be needed," wears thin, and our world seems full of neediness that can't be fixed. Those times come to caregivers of all kinds—parents, health care workers, family members of the sick or disabled, parish ministers. The morning after a particularly trying evening, I ruefully told a sympathetic co-worker, "I knew rearing these kids might be the most important thing I would do with my life, but I didn't know it would be the last thing." A mother herself, she nodded with real empathy. On the bus ride home, an elderly neighbor who cares for her bedridden husband confessed, "I feel so bad

when I get curt and impatient sometimes at the end of the day."

My role as a parish minister of the Eucharist is a very important part of my spirituality and vision of the Church. Most of the time, I am energized by my visits to the sick—until that lovely Sunday afternoon when everyone else is at the beach and the tabernacle key isn't where it's supposed to be. I've come to think of those moments as a chance to look at the underside of the diamond of caregiving, an opportunity to examine the facets that usually don't show. Borrowing Jesus' metaphor, I have come to think of these meditations as signposts for shepherds in the far pasture. They have helped me and I hope they will help to nurture and sustain you in your work of providing companionship, counsel, and consolation to those you care for.

"Jesus said to him, 'If you wish to be perfect, go, sell your possessions...then come follow me.' When the young man heard this word, he went away grieving, for he had many possessions."

Matthew 19:21,22 NRSV

On a recent blazing hot summer day, my son and I walked to a nearby shopping center. Near our destination, we found ourselves being "buzzed" by two landlocked sandpipers. At the shore, their staccato march back and forth in the surf is entertaining, but here they shrieked frantically as they alternately dived at our heads and flopped awkwardly on the hot pavement. Then we noticed the reason for their worry. Three stairstep fledglings, ranging from a tiny ball of fluff to half grown, had

scattered in all directions and were determinedly foiling their parents' best and loudest efforts to corral them. My son and I joined the round-up. For a time, that only excited the little ones and confused the parents. Finally we managed to capture the offspring and move them to a shaded strip of grass and bushes. After all that work, I half expected some sign of relief or rest from the adult sandpipers. Not so. They flew off to continue their squawking and pacing on another corner of the parking lot.

On our return, the fledglings were gone without a trace.

None of my reflections on the incident had to do with the worry and toil-free life of birds who, as Jesus tells the story, "neither sow nor reap." In fact, I had a good bit more empathy for them than envy, as I turned to see my own offspring vanish into traffic. What did occur to me was how difficult and complicated caregiving can be. What does it mean to be responsible for a child or aging parent who is, in my mother's vernacular, "independent as a hog on ice?" In health care, patient autonomy is an increasingly important value. We struggle to do well by patients even when that involves educating and empowering them to the point that they sometimes disregard our advice. As a shepherd, do I follow my lambs through the stormy dark of the far pasture and bear them back from danger, or do I "simply" issue warnings about the dangers as I see them?

The path to an answer—if there is one—is complicated by the paradox that those we care for often intuitively know what kind of care they need. At the least, they know what kind of care

"As a shepherd, do I follow
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they will accept. As a result, our best informed and most caring interventions are sometimes erroneous or inadequate...or ignored. So while we scurry frantically around and through our children's, parents', and patients' needs, they may fend us off and then fly off gracefully on their own.

I generally think of the Ministry of Presence as focusing on empathy, on reaching out to those we serve in their struggles and conflicts, on not distracting ourselves about finding the "right words" or saying the "right thing." My musings on the sandpipers have led me to suspect that an equally difficult aspect of the Ministry of Presence is to listen intently to others' thoughts and plans without becoming distracted and carried away by my wishes and plans for them, without giving my advice and sharing my experience prematurely. Somehow, that sounds easy. In practice? Well, I really wanted to tell those sandpipers that if they had built their nest in a sensible place...

Dearest Lord, perhaps it is because there are so few absolute answers and guarantees in the work of caregiving that I embrace with enthusiasm those times when I am sure my answer is right or that my advice will make a difference to those I love and care for. Give me the wisdom to know when my advice is appropriate, and the prudence to know how to blend support and silence. Amen. □

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Description: Yohimbine is a 3a-15a-20B-17a-hydroxy Yohimbine-16a-carboxylic acid methyl ester. The alkaloid is found in Rubaceae and related trees. Also in Rauwolfia Serpentina (L) Benth. Yohimbine is an indolalkylamine alkaloid with chemical similarity to reserpine. It is a crystalline powder, odorless. Each compressed tablet contains (1/12 gr.) 5.4 mg of Yohimbine Hydrochloride.

Action: Yohimbine blocks presynaptic alpha-2 adrenergic receptors. Its action on peripheral blood vessels resembles that of reserpine, though it is weaker and of short duration. Yohimbine's peripheral autonomic nervous system effect is to increase parasympathetic (cholinergic) and decrease sympathetic (adrenergic) activity. It is to be noted that in male sexual performance, erection is linked to cholinergic activity and to alpha-2 adrenergic blockade which may theoretically result in increased penile inflow, decreased penile outflow or both.

Yohimbine exerts a stimulating action on the mood and may increase anxiety. Such actions have not been adequately studied or related to dosage although they appear to require high doses of the drug. Yohimbine has a mild anti-diuretic action, probably via stimulation of hypothalamic centers and release of posterior pituitary hormone.

Reportedly, Yohimbine exerts no significant influence on cardiac stimulation and other effects mediated by B-adrenergic receptors, its effect on blood pressure, if any, would be to lower it; however no adequate studies are at hand to quantitate this effect in terms of Yohimbine dosage.

Indications: Yocon[®] is indicated as a sympathicolytic and mydriatic. It may have activity as an aphrodisiac.

Contraindications: Renal diseases, and patient's sensitive to the drug. In view of the limited and inadequate information at hand, no precise tabulation can be offered of additional contraindications.

Warning: Generally, this drug is not proposed for use in females and certainly must not be used during pregnancy. Neither is this drug proposed for use in pediatric, geriatric or cardio-renal patients with gastric or duodenal ulcer history. Nor should it be used in conjunction with mood-modifying drugs such as antidepressants, or in psychiatric patients in general.

Adverse Reactions: Yohimbine readily penetrates the (CNS) and produces a complex pattern of responses in lower doses than required to produce peripheral a-adrenergic blockade. These include, anti-diuresis, a general picture of central excitation including elevation of blood pressure and heart rate, increased motor activity, irritability and tremor. Sweating, nausea and vomiting are common after parenteral administration of the drug.^{1,2} Also dizziness, headache, skin flushing reported when used orally.^{1,3}

Dosage and Administration: Experimental dosage reported in treatment of erectile impotence.^{1,3,4} 1 tablet (5.4 mg) 3 times a day, to adult males taken orally. Occasional side effects reported with this dosage are nausea, dizziness or nervousness. In the event of side effects dosage to be reduced to 1/2 tablet 3 times a day, followed by gradual increases to 1 tablet 3 times a day. Reported therapy not more than 10 weeks.³

How Supplied: Oral tablets of Yocon[®] 1/12 gr. 5.4 mg in bottles of 100's NDC 53159-001-01 and 1000's NDC 53159-001-10.

References:

1. A. Morales et al., New England Journal of Medicine: 1221, November 12, 1981.
2. Goodman, Gilman — The Pharmacological basis of Therapeutics 6th ed., p. 176-188. McMillan December Rev. 1/85.
3. Weekly Urological Clinical letter, 27:2, July 4, 1983.
4. A. Morales et al., The Journal of Urology 128: 45-47, 1982.

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Carolina Physician's Bookshelf

Edward C. Halperin, M.D., Deputy Editor

Imai, Masaaki. *Kaizen: The Key to Japan's Competitive Success*. New York: McGraw-Hill Publishing Company, 1986.

Cheaney, Lee; Cotter, Maury. *Real People, Real Work: Parables on Leadership in the '90s*. Knoxville: SPC Press, 1991.

It seems that everywhere I turn I run into the issue of "Total Quality Management"—also known as TQM. This summer I attended a course on new developments in academic administration. Half the time was devoted to the use of TQM as a management tool in universities. After I got back to Durham I was greeted with notices that Duke Medical Center was undertaking a major initiative in TQM. Meetings were organized, lectures called, and committees formed. I've been working this semester at North Carolina State University in Raleigh. Shortly after my arrival I was assigned to a TQM study group. Various units of the university are planning on "embracing" TQM as part of N.C. State's plan to improve and streamline management.

What is TQM and why is it being seized upon by hospital and academic administrators? In the 1950s and '60s the TQM strategy was introduced in Japan by the American management experts W.E. Deming and J.M. Juran. They found a willing and receptive audience, and large portions of Japanese heavy industry adopted Deming and Juran's recommendations. Defenders of TQM would have us believe that the rest is history. Spurred on by TQM, Japan moved to a leadership position in electronics, automobile production, cameras, and copiers. For the United States an unfavorable balance of trade and a national soul-searching have been the result.

Deming and Juran's views were certainly not magic. They argued that most problems in organizations were attributable to

processes and not people. Consider, by way of example, a common hospital problem: the extended amount of time it takes to get a patient, admitted via the emergency room, upstairs into a hospital bed. Faced with prolonged waiting times, the American hospital administrator would likely look to find out "whose fault it is" and reprimand or fire him or her. The TQM manager, on the other hand, would begin by examining the process by which patients get moved from the emergency room to the hospital floor and try to understand how the process is dysfunctional. In other words, the TQM manager begins from the premise that most workers try to do the right thing and that if failure occurs you look at what's wrong with the system, not with the worker.

Facing the emergency room problem, the TQM manager would assemble a "cross-functional team." These teams consist of individuals from various departments. The team is based on the notion that the important person in the process is the "customer" (the patient waiting on the stretcher), and not the bureaucratic defense of "the department." The team also is illustrative of another important part of TQM—improved organizations result from the work force making suggestions for improvement and buying-in to the solutions rather than management, from the top-down, ordering change.

The TQM team would tackle the emergency room problem by precisely describing the problem, brainstorming about possible causes, creating flow charts to describe the current process by which patients get transferred to the floor, and deciding what data needs to be compiled. They would then go out and compile that data (i.e. how long patients are kept waiting at various points in the process, who is being asked to sign forms, how many people are involved in accomplishing each step). The team would then re-assemble to study the data, find out where duplication and unnecessary effort is being expended, and recommend corrective measures. The corrective measures would then be implemented, the results re-monitored, and the process repeated. By continuous improvement, or in Japanese: *kaizen* (ky'zen), the emergency room problem would be gradually whittled away.

From the Division of Radiation Oncology, Box 3085, Duke University Medical Center, Durham 27710.

The crucial elements of TQM are, therefore, that it involves the line workers in addition to the managers, that it is collegial, that it is willing to accept small incremental change rather than demanding great leaps, that it is heavily data-based, and that it relies on flow charts, matrix graphs, cause-effect diagrams, and hours of meetings. It may be a better way to build Toyotas, but can you run a hospital, medical school, or university this way?

I don't know. Many of the things we do in hospitals are not amenable to precise statistical evaluation, i.e. How compassionate are we? How good are we at teaching the residents? This excuse is, however, limited. Hospitals certainly have many functions that are close to those of business and could benefit from business techniques. The billing office, cafeteria, equipment purchasing, building and grounds department, and other functions might be quite suitable for TQM management. Since so many people seem to be seizing upon TQM and its tools, I suppose we'll soon find out if it works.

Masaaki Imai is a management consultant and an unabashed devotee of TQM. His book is laced with laudatory prose, glowing case examples of TQM's triumphs, disparaging comments about the method's detractors, and little practical guidance for use of the technique outside of heavy industry. By failing to provide the reader with a critical review of the subject, Imai fails in an attempt to write a definitive and sole text.

Cheaney and Cotter have worked in government and universities. Their TQM book, *Real People, Real Work*, is a collection of cute vignettes of work situations that could stand a dose of concern for the customer and consideration of how processes could be improved. This paperback is most suitable as a supplemental text for discussion used alongside a heavier tome.

As I have been thinking about TQM for the past few months, I often conclude that it is really nothing more (and nothing less) than fundamental good management dressed up with graphs and some Eastern philosophy and culture. As someone who has had his share of waiting in line while being ignored by a clerk, I can't help but applaud any management strategy that would get workers to pay more attention to the needs of the customer. If it takes TQM to do that, I'm all for it!

McBryde Jr., Angus M.; Spence, Read McBryde.
A History of the North Carolina Orthopedic Hospital:
A Dream Come True. Charlotte: Washburn Press,
1991, \$10 (available from R.M. Spence,
3406 Round Hill Road, Greensboro, NC 27408)

From 1921 to 1979 the North Carolina Orthopedic Hospital in Gastonia operated as a publicly supported institution for children requiring medical and surgical care of musculoskeletal deformities, osteomyelitis, clubfoot, scoliosis, tuberculous joints, and polio. Over the years the spectrum of diseases changed, but not the patience, care, and commitment of the staff. McBryde and Spence provide a warm and gentle reminiscence of the good

times and bad times at the hospital along with pleasant black-and-white illustrations. I'm sure that this 86-page monograph will bring a few memories to the surface for those physicians who had an association with the Orthopedic Hospital.

Monroe, Gary L. A Handbook for:
The Traveling Freelance Physician.
Houston: Magellan Publishing Company, 1990, \$75.

This book contains everything you wanted to know about being a locum tenens physician but were afraid to ask. How do you market yourself? How much do those little Rolodex cards cost with your name on it? Are they better to use than running a classified advertisement in the medical journals? When should you be paid? How do you prepare a contract? What sort of motel should you stay in while you're on assignment?

Dr. Monroe's underlying theme is that you don't have to use a locum tenens placement company if you're interested in working as a freelance physician. He says that you can market yourself and pocket the placement fee instead. His loose-leaf bound book reads like a one-hour chat (that's about how long it takes to read) with a locum tenens physician about life on the road.

Residency program directors or hospital libraries might consider having a copy of this book on hand when the residents stop in looking for advice about making some money by doing locum tenens during vacations. At \$75 a copy, however, I'd be restrained at recommending bulk purchases.

Hanson, Frederick M. Our Doubts Are Traitors.
New York: Vantage Press, 246 pages, \$16.95.

Reviewed by Connie Hall Meares,
Hampton Court, Chapel Hill.

You've probably seen the advertisement in a magazine: "Authors....looking for a publisher?" The advertisement invites inquiries to Vantage Press of New York. Vantage is a so-called "vanity press." If your book has been turned down by a commercial publisher Vantage will publish your book—for a fee. *Our Doubts Are Traitors*, published by Vantage, tells the story of a young doctor who loses his confidence after his perceived failure to diagnose his fiancée's brain tumor in time to save her. He gives up his dream of becoming a neurosurgeon and moves to a small North Carolina town, Bennettsboro, where he opens a general practice. Here the Shakespeare-loving doctor becomes involved with both the townspeople and his nurse—discovering much about both. They in turn help him rediscover himself. The last to discover anything will be the

reader who will, in all likelihood, have given up on all this tedium by this point. The story takes place mainly in Bennettsboro but there are several scenes in Durham and at Duke Hospital.

tients did better" just won't do. Stewart and Ware's selected authors have made a worthwhile contribution to the literature.

New Books Briefly Noted

Stewart, Anita L.; Ware, Jr., John E., editors.
Measuring Functioning and Well-Being.
Durham: Duke University Press, 1992.

The Medical Outcomes Study used a variety of measures to assess the results of therapy. The methodological underpinnings of the study are addressed in this lengthy (448 pages of close type) volume. Functional measurements are terribly important and are often not given enough attention. I think we don't spend enough time measuring, in a critical way, our ability to obtain pain relief with analgesics or functional improvement in people with joint problems, for example. In rigorous clinical trials simple pronouncements that "the pa-

Wynn, Margaret; Wynn, Arthur. **The Case for Preconception Care of Men and Women.**
Bicester: AB Academic Publishers, 1991.

Neither of the authors are physicians. They argue that preconception behavior of men and women influence pregnancy outcome.

U.S. Department of Human Services. **Health Care Financing; Status Report: Research and Demonstrations in Health Care Financing, Fiscal Year 1989 Edition.**
Baltimore: HCFA Publication Number 03304, 1990, \$7.

The Health Care Financing Administration spends a significant amount of money on studies of the impact of Medicare and Medicaid. This paperback is a listing of current studies underway along with status reports. □

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Continuing Medical Education

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7th Annual Sports Medicine Symposium for Primary Care Physicians

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Credit: 11 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

December 4-5

Current Urologic Update

Place: Winston-Salem
Credit: 9 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

December 5

UNC Ophthalmology Residents Day

Place: Chapel Hill
Credit: 3.5 hours Category I, AMA
Info: Christine C. Cotton, UNC Department of Ophthalmology, CB #7040, 617 Burnett-Womack Bldg., Chapel Hill 27599-7040. 919/966-5296

December 5

4th Annual Lipid Symposium

Place: Research Triangle Park
Info: Office of CME, DUMC, Durham 27710. 919/684-6485

December 7-8

Mammography Minifellowship

Place: Winston-Salem
Credit: 16 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

December 8

Geriatric Medicine: Primary Care Evaluation and

Management Strategies

Place: Raleigh
Credit: 6 hours Category I, AMA
Fee: \$40
Info: Kim Leadon, Director of CME, Wake Area Health Education Center, P.O. Box 14465, Raleigh 27620-4465. 919/250-8030

December 9-11

1992 Health Promotion and Wellness Institute—Community Interventions in Tobacco Control: Strategies on the Cutting Edge

Place: Raleigh
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill 27599-8165. 919/966-4032

December 9-11

Getting the Message Across for Environmental Health Specialists

Place: Kure Beach
Info: Office of Continuing Education, UNC School of Public Health, CB #8165, Chapel Hill 27599-8165. 919/966-4032

December 11

Update on Mood Disorders

Place: Chapel Hill
Credit: 6.5 hours Category I, AMA
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

January 11-15

Neurovascular Ultrasound

Place: Winston-Salem
Credits: 25 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

January 14-15

1993 Annual Geriatric Conference

Place: Chapel Hill
Info: Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

January 14-15

ACLS Retraining Course

Place: Raleigh
Credit: 8 hours AAFP
Fee: \$75
Info: Helen Creech, R.N., Course Coordinator, Rex Hospital, 4420 Lake Boone Trail, Raleigh 27607. 919/783-3161

January 15

Critical Care Update

Place: Chapel Hill
Credit: 12 hours Category I, AMA
Info: Nancy Barnes, Office of CME, UNC School of Medicine, CB #7000, 231 MacNider Bldg., Chapel Hill 27599-7000. 919/962-2118

January 18-19

Mammography Minifellowship

Place: Winston-Salem
Credit: 16 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

January 18-22

Adult Echocardiography

Place: Winston-Salem
Credit: 25 hours Category I, AMA
Info: Division of Continuing Education, Bowman Gray School of Medicine, Winston-Salem 27103. 919/716-4450

January 21
North Carolina Health
Law and the Physician

Place: Research Triangle Park
Credit: 3 hours Category I, AMA
Info: Kim Leadon, Director of CME,
Wake Area Health Education
Center, P.O. Box 14465,
Raleigh 27620-4465.
919/250-8030

January 21-22
Improving Clinical Education:
Teaching, Evaluation and Feedback

Place: Chapel Hill
Credit: 12 hours Category I, AMA
Info: Nancy Barnes, Office of CME,
UNC School of Medicine, CB
#7000, 231 MacNider Bldg.,
Chapel Hill 27599-7000.
919/962-2118

January 22
Neurology Day

Place: Greenville
Credit: 7 hours Category I, AMA
Info: Mary C. Valand, Office of Con-
tinuing Medical Education, Box
7224, Greenville 27835-7224.
919/551-5208

January 25-29
Peripheral Vascular Ultrasound

Place: Winston-Salem
Credit: 25 hours Category I, AMA
Info: Division of Continuing Educa-
tion, Bowman Gray School of
Medicine, Winston-Salem
27103. 919/716-4450

February 8-12
Radiological Ultrasound

Place: Winston-Salem
Credit: 25 hours Category I, AMA
Info: Division of Continuing Educa-
tion, Bowman Gray School of
Medicine, Winston-Salem
27103. 919/716-4450

February 12
Third Annual Public Health
Social Work Seminar Series

Place: Greenville
Info: Office of Continuing Education,

UNC School of Public Health,
CB #8165, Chapel Hill 27599-
8165. 919/966-4032.

February 15-17
Selected Topics for the
Practicing Clinician

Place: Durham
Info: Office of CME, DUMC,
Durham 27710. 919/684-6485

February 19 & 20
Pediatric Advanced
Life Support Course (PALS)

Place: Raleigh
Credit: 16 hours Category I, AMA
Fee: \$200
Info: Kim Leadon, Director of CME,
Wake Area Health Education
Center, P.O. Box 14465,
Raleigh 27620-4465.
919/250-8030

February 22-26
MRI Minifellowship

Place: Winston-Salem
Credit: 32 hours Category I, AMA
Info: Division of Continuing Educa-
tion, Bowman Gray School of
Medicine, Winston-Salem
27103. 919/716-4450

February 26
The Rafael C. Sanchez
Family Medicine Annual Update

Place: Greenville
Credit: 7 hours Category I, AMA
Info: Mary C. Valand, Office of Con-
tinuing Medical Education, Box
7224, Greenville 27835-7224.
919/551-5208

March 1-4
The Alton D. Brashear Postgraduate
Course in Head and Neck Anatomy

Place: Richmond, VA
Credit: 40 hours Category I,
AAGP/AGD
Info: Dr. Hugo R. Seibel, Department
of Anatomy, Box 709, Medical
College of Virginia, Richmond,
VA 23298.

Invited Comments on
"The Physician's Oath"
continued from page 628

Despite these comments, Dr. Boyd makes many cogent, but less controversial, points in his "Oath." He recognizes the power of a firm patient-physician relationship and the confidence and potential healing power that goes with this union. He implores the physician to recognize and redress any educational or experiential deficiencies and the importance of consultation and referral. He makes a plea for quality assurance and constant self-evaluation in medicine. He applauds the importance of informed consent and the necessity of patients taking responsibility for their own health. He recognizes physician responsibility toward social improvement and health care policy.

In my opinion, Dr. Boyd's attempt to redefine the ethical and moral principles for the modern, and perhaps new, physician falls short of the mark. The precision of the document leaves little room for individual interpretation and precludes the ability to select a pathway from the pillars of medical ethics. Personal ideology is espoused without a definition of justification. Thus, I will apologize for his apology. □

"The critical sense and sceptical attitude of the Hippocratic school *laid the foundation of modern medicine on broad lines,** and we owe to it: first, the emancipation of medicine from the shackles of priestcraft and the caste; secondly, the conception of medicine as an art based on accurate observation, and, as a science, an integral part of the science of man and of nature; thirdly, *the high moral ideals expressed in that most 'memorable of human documents,' the Hippocratic Oath*...*"

—Sir William Osler,
"Chauvinism in Medicine," 1902
(*emphasis added by Dr. Chitwood)

Acknowledgment: The author thanks Dr. Edmund D. Pellegrino for discussing this subject with him.

Two Days in the Life Of a Mini-Internship

Patricia K. Hodgson and Edward McG. Hedgpeth, Jr., M.D.

A mini-internship takes community leaders and puts them into the delivery side of health care for two solid, back-to-back days. The days are understandably intense for the interns but are expected to be "routine" for the doctors, who are asked not to gerrymander their schedules in any way. Among the types of people invited to participate in mini-internships are county commissioners, city council members, hospital trustees, clergy, company benefits managers, attorneys, insurance executives, representatives of the media, and, of crucial importance, senators, representatives and/or their senior staff in both the North Carolina General Assembly and the United States Congress. Those are the people who either *make* policy that regulates the way medicine is practiced or are in a position to *affect* such policy or public opinion about it. It is vital for them to understand the realities of medical care from the provider's side as well as the recipient's side.

The North Carolina Medical Society sponsored its pilot mini-internship program in Durham early in 1990. The Durham-Orange County Medical Society has conducted three others since then, recently establishing a routine of two each year, one in the spring and one in the fall. Mini-internship programs are, without question, the single most successful way any medical society can teach non-physicians about what it is like to deliver medical care in today's hassle-filled, litigious world.

Here we describe the most recent Durham-Orange mini-internship, which took place on September 23 and 24, 1992. The accompanying article by Jeanne Yohn (page 667), managing editor of the *Journal*, reflects her two-day experience as an intern. We also attempt to convey the philosophy behind mini-internships, why they are important, how they work, what they cost, and why you should initiate one in your community.

The Planning Stage

The Mini-Internship Committee* of the Durham-Orange County Medical Society met twice, first on July 8th and again on September 8th, 1992. Both meetings took place in the evening and lasted about two hours. At the July 8th meeting, the Committee set September 23rd and 24th as the dates of the mini-internship program they were planning. Breakfast was scheduled for September 22nd, the day preceding the first day of the program, and a concluding dinner was scheduled for September 24th, the last day of the program. Names of possible interns were suggested until we had a list of more than 50 names. Our target was to have between eight and 12 interns, but experience has shown us that we need to invite three to four times that number since many people find it difficult to take two successive days away from their work without a great deal of notice. From the list of 50, we chose 15 people to invite first and ranked the remaining names so that we could simply invite another person each time someone declined.

Letters inviting the first 15 potential interns were sent on July 27 and requested a response within two weeks. Six of the 15 responded positively, but two later found that they had a conflict on the evening of September 24th, and asked if they could defer, to be included next time. Eight of the nine who were unable to participate expressed a desire to be involved at a later date. Not all of the invited interns responded within the two weeks, and so we resorted to telephoning to determine their

*The Committee: James L. Allen, M.D., obstetrician/gynecologist; Paul S. Andrews, M.D., obstetrician/gynecologist; Woodrow W. Burns, M.D., general surgeon; Robert E. Price, M.D., neurosurgeon; and Edward McG. Hedgpeth, Jr., M.D., ophthalmologist, chairman.

Ms. Hodgson served as communications director of the North Carolina Medical Society when the September 1992 mini-internship took place. Dr. Hedgpeth, an ophthalmologist at the North Carolina Eye and Ear Hospital, 1110 W. Main St., Durham, 27701, is chairman of the Medical Society's Communications Committee.

interest and availability.

A second group of invitation letters was sent on August 13 to six people; none were available but five asked to do it another time. The last group of invitations went to nine people on August 21 and 24; four accepted, a fifth asked to be considered another time. We had eight interns in the fold and September fast approaching. We stopped there and called the second meeting of the Committee. We had invited 30 people and gotten eight participants, but we also had a group of 16 people who wanted to take part in the next program early in 1993.

The Match

The Committee met on September 8th to match the eight interns with eight physicians. Table 1 (right) lists the names of the interns and the kind of information the Committee took into consideration in deciding what kind of experiences each intern should have and why. Mr. Metzloff, for example, has a research interest in professional malpractice and dispute resolution. The Committee felt that it would be useful for him to spend a day in a high-stress medical or surgical situation as well as to have an office-based day. Ms. Yohn

has years of experience working with publications but almost none working with physicians, and the Committee felt that she should see a broad range of medical care in her two days. Mr. Crumpton's company insures many medical professionals in North Carolina. The Committee wanted him to know about and to understand the pressures those doctors encounter in their work.

Eight doctors were chosen by the Committee to match the eight interns, and each Committee member agreed to call one or two of those doctors, to explain the program to them and ask them if they would take part. Due to vacation plans and a

competing laparoscopy course, it was more difficult than usual to lock in the eight doctors. This is ordinarily the easiest part of the planning since the participating physicians have only to do what they normally do in their practice but be willing to have someone looking over their shoulder for two days. The mini-internship program has gained a reputation among Durham-Orange County Medical Society members as a worthwhile endeavor that requires little "extra" from the physician participants while giving them the interesting intellectual challenge of hosting an intelligent observer for two days and the pleasure of hearing at the closing dinner how the interns viewed their experiences.

One important element in the Durham-Orange Society's mini-internship program is our effort to give each intern one day either in the operating room or with a physician doing such invasive procedures as endoscopies, laser surgery, or cardiac catheterizations.

The other day is spent with either a primary care physician or a surgeon seeing patients in the office rather than operating. Other medical societies across the country put their own spin on how the interns spend their days and with whom, and virtually everyone is pleased with the way their program works.

A second matter of importance is the necessity of matching obstetrician/gyne-

cologists with women interns and urologists with men.

Table 2 (right) gives the names and specialties of the eight doctors, the interns with whom they were matched, and how and where they planned to start each of the two days.

The Mini-Internship Program

On Tuesday morning, September 22, seven of the eight interns and six of the eight doctors met for breakfast at 7 a.m. in a small dining room at the Washington Duke Inn in Durham. One intern



The September 1992 mini-Internship group. Seated from left: Cathy W. Thomas, M.D., Dorothy M. Bell, M.D., Chancy M. Kapp, and Jeanne C. Yohn. Standing from left: T. Craig Derian, M.D., Robert A. Beason, Edward McG. Hedgpeth, Jr., M.D., William O. King, Robert A. Buchanan, M.D., Samuel A. Mason, Abe Walston, II, M.D., Thomas B. Metzloff, Lawrence W. Moore, Jr., M.D., J. Slade Crumpton, and D.G. Martin. Missing: Walter E. Davis, M.D., and Philip H. Pearce, M.D.

Table 1. The eight interns

Robert A. Beason, an attorney who handles domestic, criminal, and personal injury cases with Maxwell & Hutson in Durham

J. Slade Crumpton, president and chairman of the Crumpton Company, a privately held corporation specializing in insurance for professionals and trade associations, located in Durham

Chancy M. Kapp, associate director for programming at the UNC Center for Public Television in Research Triangle Park

William O. (Bill) King, an attorney with special areas of practice in personal injury, wrongful death, family, and malpractice law with King, Walker, Lambe & Crabtree in Durham

D.G. Martin, Jr., an attorney and secretary of the Consolidated University of North Carolina, headquartered in Chapel Hill

The Rev. Samuel A. Mason, rector of St. Stephen's Episcopal Church in Durham

Thomas B. Metzloff, professor of law currently teaching courses in professional liability, professional ethics, alternative dispute resolution, and civil procedure at the Duke University School of Law in Durham

Jeanne C. Yohn, managing editor of the official organ of the North Carolina Medical Society, the *North Carolina Medical Journal*, which is edited in Durham

Table 2. Matrix of doctors and interns

Intern	Wednesday, September 23	Thursday, September 24
Robert A. Beason	Dorothy M. Bell, M.D. ophthalmology 7:50 a.m. surgery NC Eye & Ear Hospital	Robert A. Buchanan, M.D. internal medicine/invasive cardiology 8:15 a.m. rounds Durham Regional Hospital
J. Slade Crumpton	Robert A. Buchanan, M.D. internal medicine/invasive cardiology, 8:15 a.m. rounds Durham Regional Hospital	Dorothy M. Bell, M.D. ophthalmology 8:20 a.m. office NC Eye & Ear Hospital
Chancy M. Kapp	Abe Walston, II, M.D. internal medicine/cardiology 8 a.m. treadmill Durham Regional Hospital	Philip H. Pearce, M.D. obstetrics/gynecology 8 a.m. Roxboro satellite office Durham Women's Clinic
William O. (Bill) King	Cathy W. Thomas, M.D. anesthesiology 7 a.m. surgery, Durham Ambulatory Surgery Center	Lawrence W. Moore, Jr., M.D. ophthalmology 8:30 a.m. Roxboro office NC Eye & Ear Hospital
D.G. Martin, Jr.	T. Craig Derian, M.D. orthopaedic surgery 7:30 a.m. discograms Durham Regional Hospital	Abe Walston, II, M.D. internal medicine/cardiology 8 a.m. rounds Durham Regional Hospital
Samuel A. Mason	Walter E. Davis, M.D. hematology/oncology 7:30 a.m. rounds Durham Regional Hospital	T. Craig Derian, M.D. orthopaedic surgery 8:15 a.m. office Durham Clinic
Thomas B. Metzloff	Lawrence W. Moore, Jr., M.D. ophthalmology 8:15 a.m. office NC Eye & Ear Hospital	Cathy W. Thomas, M.D. anesthesiology 7 a.m. surgery Durham Regional Hospital
Jeanne C. Yohn	Philip H. Pearce, M.D. obstetrics/gynecology 8:20 a.m. rounds Durham Regional Hospital	Walter E. Davis, M.D. hematology/oncology 7:30 a.m. rounds Durham Regional Hospital



Left: Thomas B. Metzloff, law professor, examines Mrs. Mildred F. Woodward's cataract under the watchful guidance of Lawrence W. Moore, Jr., M.D., ophthalmologist at North Carolina Eye & Ear Hospital. **Right:** From left, Abe Walston, II, M.D., Robert A. Buchanan, M.D., and D.G. Martin listen to Thomas Metzloff explain that although he has such an uncanny ability to sense the correct time that he doesn't wear a watch, "at 10:30 this morning I thought it was time to go home." That was the day he spent with Cathy W. Thomas, M.D. (right), an anesthesiologist with Durham Anesthesia Associates.

was out of the state on business but was contacted later that day and given the final details about the program. One of the two missing physicians had surgery beginning at 7 that morning, and the other was up all the previous night with an intestinal virus, which he was thoughtful enough not to spread to the assembled participants at breakfast.

Almost all the doctors knew one another and some of them knew one or two of the interns personally, but the breakfast went smoothly even for those who were strangers. Until they finished eating and had the few remaining pieces of the internship mapped out for them, no one in the room knew with whom or where he or she would spend the next two days.

After breakfast, Dr. Hedgpeth gave an overview and a little bit of the history of the mini-internship program, saying that the greatest thing about it was the "it opens all the doors that say 'no admittance' for these two days," and that it was an experience that couldn't be had in any other way. As the interns' packets were passed out to them they were told that the patient-physician relationships they were going to witness and be a part of were "confidential and privileged." For that reason each intern was required to sign a confidentiality form, promising not to reveal the names and/or identifying details about any of the patients they had seen.

The doctors' packets contained written informed consent

forms that the doctors could use with their patients if they wished. Alternatively, they could explain to each patient that the intern was present on a medical society-sponsored program and ask verbal permission for the intern to be present during the appointment. Most operative permits usually allow the presence of consultants or other observers during surgery (and lay interns generally fit the description of "observers"), but the physicians were reminded about the need for their OR permit to cover the interns as well.

The packets also contained a brief resumé about each participant, and, of greatest interest to the group, personalized schedules for each intern and doctor for the next two days. Although the schedules explained where and at what time the two-somes were to meet on the following two mornings, everyone was advised to touch

"...the greatest thing about (the mini-internship program) was that it opened all the doors that say 'no admittance' for these two days, and that it was an experience that couldn't be had in any other way."

base with their host or guest before leaving the breakfast. As the participants stood to introduce themselves to the group, the interns were given white lab coats to wear during the program; each one had an intern's name tag on it.

Beginning as early as 7 a.m. Wednesday, September 23rd, the interns and their mentors met and went about the business of medicine. Thursday, September 24th, was more of the same with one importance difference: the dinner that evening would conclude the program and, if it held true to the pattern established earlier, would be the perfect capstone.

Diary of a Mini-Intern

By Jeanne C. Yohn, Managing Editor, NCMJ

The young woman who walked into Dr. Walter Davis's office for an afternoon consultation appeared apprehensive but composed, hoping that the recent removal of her right breast had eradicated the cancer that had prematurely invaded her 32-year-old body. Her surgeon had referred her to Dr. Davis, who was to evaluate her condition and formulate a course of follow-up care. In my role as mini-intern, I listened intently and observed Dr. Davis begin a typical "day at the office."

He began by asking the woman a litany of questions about her health history. She answered them dutifully, allowing her mother, seated nearby, to elucidate some points. I was impressed by her candor and honesty in my presence; perhaps the white coat I was wearing gave me some measure of credibility.

After directing her to an examination room, Dr. Davis asked me to walk down the hall with him to confer with the attending surgeon, whose office is in the same clinic. On the way, I crossed my fingers that the woman, just a few years older than I, would be spared any further complications from the lump she had discovered in her breast. Unfortunately, she wasn't so lucky. Despite the complete removal of her breast, the surgeon noted that there was a 90% to 95% chance that the cancer would recur if aggressive treatment was not implemented.

It was now up to Dr. Davis to deliver this grim news. I tried to imagine how he would deliver it and how the woman might react. Having once worked as a newspaper reporter, I recalled being present with a notepad during a few heart-wrenching episodes when families were told that their loved one had perished in a car wreck or was sentenced to life in prison. During my reverie, we walked back to the examination room, where Dr. Davis listened to the woman's heart and lungs and examined her rapidly healing surgical site.

Back in his office, Dr. Davis didn't waste time with small talk. He spoke earnestly and directly to his patient, explaining the likely probability that the cancer would recur. The woman nodded, expressionless, her eyes betraying anguish and disappointment. I expected her to cry; she didn't. I attributed her courage to two factors: her mother was there and Dr. Davis was able to summarize sophisticated procedures in terms that she could understand. I knew that doctors are trained to do this and hone their skills throughout years of practice. Witnessing it, however, was enlightening. His gentle but forthright demeanor certainly seemed to soften a psychological bombshell by helping to clarify the physical aspects of the disease.

Dr. Davis recommended that the woman consider having an autologous bone marrow transplant. Developed by physicians at Duke University, this experimental program involves taking bone marrow from the patient, treating the patient with massive doses of chemotherapy, and then infusing the marrow back to the host. Characterizing the treatment as "investigational," Dr. Davis told her that it had significantly reduced the chances of recurrent cancer in other patients. The woman

brightened and looked hopeful; she and her mother asked many more questions before leaving that day. Dr. Davis undoubtedly had given them plenty to ponder.

After observing several more patient visits and reflecting on our morning rounds at Durham Regional Hospital, I asked Dr. Davis why he practices oncology and how he copes with caring for the chronically ill. He said that when he decided to become a doctor he knew that he wanted to treat people who were genuinely sick, not what he called "the worried well," or people complaining of less life-threatening maladies. Practicing oncology and hematology, he said, suited his purpose and personality.

Dr. Philip Pearce, the ob/gyn I had spent the previous day with, had a decidedly different story about how he chose his specialty. After training as a surgeon at Duke, he headed to Newfoundland for a tour of duty as a general medical officer at an air force base. During his second year, Dr. Pearce and two of his colleagues were asked to decide among themselves who would fill the position left vacant by a departing ob/gyn. No one volunteered, so the senior staff physician appointed Dr. Pearce to the post. After a year spent treating families at the base, Dr. Pearce was convinced that he had found his calling in medicine.

Throughout my two-day stint, I was amazed at the doctors' stamina and their ability to balance the role of healer with their duties as manager and problem-solver. My job requires me to familiarize myself with the basic socioeconomic issues in medicine, so I knew that Dr. Davis and Dr. Pearce were responsible for far more than just patient care. It surprised me, though, to see the extent to which they are frequently obligated to unravel the bureaucratic gridlock of insurance claims, medical billing procedures, and staff management.

For example, one of Dr. Davis's hospital patients was a cantankerous, elderly woman who consistently complained about the nursing care she was receiving. During rounds, she asked Dr. Davis to make sure she received a second bowl of oatmeal at breakfast. Taking her temperament into account, Dr. Davis suddenly found himself in the dual role of waiter and physician. Chuckling about it later in the nurses' station, he playfully chastised them for not bringing enough oatmeal to satisfy his patient. A little "gallows humor," he confided, keeps hospital staff from becoming overwhelmed



Dr. Pearce and Ms. Yohn

by the often depressing aspects of caring for people with cancer.

On a more humanistic level, I also found it interesting to see how much Drs. Davis and Pearce had to delve into their patients' personal lives to provide effective treatment. This was particularly evident in how Dr. Pearce cares for his roster of prenatal patients. The women we saw represented a true cross-section of social, economic, and financial strata. Since most of them worked full time, Dr. Pearce quizzed them about their work routines and stress levels—particularly those patients in their third trimester—and about their home lives.

A working mother myself, I was curious whether the evolution of the working woman has affected the way he practices obstetrics. Many women have delayed having children until they establish careers, which makes some of Dr. Pearce's patients older and at greater risk for complications like neural tube defects. Especially vulnerable to job-related stress, some of these women have developed preeclampsia, which Dr. Pearce says he has noted across all socioeconomic levels. He added that these factors, and the advent of additional requisite genetic tests, require him to spend significantly more time with each patient than he did a decade ago.

I truly appreciated the time both doctors spent answering my many practical, and sometimes philosophical, questions about their profession. After spending an incredibly hectic morning with Dr. Pearce at his clinic, I asked him over a hastily eaten "lunch" of yogurt and trail mix in his office how he balances his professional and personal lives. He recognized that because his father had been a minister, he has a profound sense of spirituality in his life. Later posing the same question to Dr. Davis, whose wife is a former nurse, it was evident that both men also attribute their physical and mental fortitude to strong and supportive families.

The public perceives doctors as healers and authority figures, but my experience also showed me that they are frequently friends and confidants. It was fascinating to watch Dr. Pearce and Dr. Davis establish rapport and forge relationships with people from so many backgrounds and cultures. On a personal note, both doctors graciously extended the same kind of warmth to me, and I never once felt that I was conspicuous or interfering with their work. Similarly, every patient that I encountered, no matter how riddled with cancer or how concerned about a problematic pregnancy, welcomed my bystander's interest in their condition. For two days, I was transformed from publications professional to Dr. Pearce's and Dr. Davis's "assistant."

Before I became managing editor of the *Journal* last year, I had worked as a writer and editor for a consumer home-building magazine in the Washington, D.C., area, but I had never helped build a house. When Ms. Hodgson and Dr. Hedgpeth invited me to participate in the mini-internship program, I jumped at the opportunity to learn more about a profession, that, until a year ago, I knew little about. I didn't have many preconceived notions about what I might gain from my two-day crash course. I only hoped that I would get an educated glimpse of how medicine is practiced by doctors in North Carolina. I came away with that, and much more. □

Prior to the dinner, the interns met with Ms. Hodgson at 6 p.m. for a one-hour reception. The original purpose of this time was to debrief the lay participants, but they arrived so eager to discuss with one another what they had seen and done that there was no opportunity to formally talk about the strengths and weaknesses of the program. From our observations of the interns as they excitedly recounted their experiences, there simply were no weaknesses.

Shortly after 7 p.m., the dinner began, with the eight interns and six of the eight doctors seated around one long table. Two doctors had unavoidable last-minute conflicts and were unable to be there. Shortly after coffee and dessert, Dr. Hedgpeth thanked everyone for their participation and invited each person in the room to tell something about the two days. As each intern and doctor in turn spoke briefly about the experience that the mini-internship program provided, a picture emerged of the same world seen differently by two sets of eyes. The doctors painted a picture of normally hectic days made more pleasurable by the company of an interested guest with whom to discuss diagnoses, prognoses, treatment options, and life in general. The interns' portrait seemed unique and precious, a one-in-a-lifetime chance to watch doctors interact with their patients and their staff and to question them closely about the situations they encountered and the advice they gave and why. Both the doctors and the interns expressed overwhelmingly positive feelings about the value of the program and the opportunity it gave them to share two days in a very special profession.

The Cost

While we give the costs of the Durham-Orange mini-internship programs, understand that it is possible to vary the cost greatly. The cost of this one (\$1,530) included rental of eight lab coats for one week (\$16), purchase of the eight name tags (\$25), breakfast, reception, and dinner for 18 people (\$1,318), photographs (\$35), and an enlargement of the group photo for each participant (\$136). Over the past three years, we have learned that budgeting \$200 per intern in the Durham-Orange County Medical Society Program gives a reasonably accurate ballpark figure.

Other medical societies in North Carolina handle the cost of their mini-internship programs differently. In Burlington, for example, a hospital hosted the breakfast, eliminating that cost entirely from the Medical Society's budget. The breakfast was also held in a hospital in Fayetteville during its first mini-internship, which occurred during the week of September 22nd, and the lab coats for those interns were donated, which not only eliminated the cost of renting them but also gave the interns another tangible reminder of their experience. In Pitt County interns are invited to bring their spouses to the concluding dinner, something we feared might not work well, but does. Mini-internship programs are in place in Charlotte and

Wilmington and are in the planning stage in other areas, notably Greensboro, which will have put on its first program by the time you read this. The North Carolina Medical Society's Communications Committee and Communications Department are committed to the spread of mini-internships throughout the state and have a simple, step-by-step instructional book as well as funds budgeted and experts available to help you plan and carry out your first program.

Why Bother?

First of all, there really isn't much bother. A secretary with an eye for detail can handle the letters and phone calls, arrange for the meals and lab coats, and put together the packets. An interested doctor and a few peers corralled into assisting can come up with a list of potential interns and doctors for the first program; after that, it's just a matter of repeating your success once or twice a year.

There is, however, an answer to "Why bother?" There is no more effective way to educate influential community leaders—persons who have access to large numbers of people and who affect, influence, report on, or carry out health care policy. Of perhaps even more importance, there is *no* other way for those influential people to know and understand what it is like to be a doctor than to walk in the doctor's shoes—almost *be* a doctor—for a couple of days. As we've learned over the past few years, interns not only glean an understanding of what is involved in doctoring; they also come quickly to appreciate its many facets, both negative and positive, and they return to their own lives enriched by what they have witnessed and proud of the physicians who serve their community.

Today—more than ever in the past but no doubt less than in the future—it is essential for health policy-makers and influencers to know firsthand the burden, stress, and hassle of providing care in a busy medical or surgical practice. In a mini-internship program they also experience the joys and sorrows of patient care, recognize the enormous commitment of time that medicine requires and often feel bone weary from the physical and emotional toll of the two days. The real benefits of the mini-internship program flow from the interns' positive reactions to the wonderful physician-patient relationships that they witness that exist, and sometimes flourish, in spite of the drawbacks imposed from outside. To hear interns talk about their unique view of medicine up close and personal, face-to-face and one-on-one is an experience every good doctor should seek and savor. *That's* why you should bother.

There's one other important factor to keep in mind as you decide whether to embark on your first mini-internship: everyone agrees that it's fun. □



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North Carolina Medical Journal

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Aphorisms of the Month

A knowledge of Sanskrit is of little use to a man trapped in a sewer.

—Tom Weller Minims* 1982

It is difficult to repair a watch while falling from an airplane.

—Tom Weller Minims* 1982

A single death is a tragedy, a million deaths is a statistic.

—Joseph Stalin

The race is not always for the swift nor the battle for the strong—but that is the way to bet.

—Damon Runyon

Futility, Failure, and Tragedy

Edited by Daniel Sexton, M.D.

Might and Right are always fighting
In our youth it seems exciting
Right is always nearly winning
Might can hardly keep from grinning

—Clarence Day

Dogs once scalded are afraid even of cold water.

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In the last year, CompuSystems' installations in North Carolina have more than doubled. And 35% of our new customers in 1990 switched from other systems to ours.

Picture your practice with CompuSystems' medical insurance processing and billing system. You'd be smiling too.

More and more North Carolina physicians are discovering that CompuSystems has a medical insurance processing and billing system worth smiling about. In fact, our North Carolina installations more than doubled last year. (And 35% percent of those were replacements: the physicians found CompuSystems offered better value and performance than their old vendor.)

So why is a computer company from South Carolina meeting with such acceptance in North Carolina? Here are some of the reasons our customers have given us:

Support, support, and support

You won't find CompuSystems' medical systems in all 50 states. In fact, you'll only find them in five. That's because we only sell our system where we can offer support that's up to our standards. (And they're high standards: according to a 1990 survey, CompuSystems' service *exceeded* customer expectations in all categories, including training, telephone support, and hardware service.)

So when you have a question, we respond. With software support available every business day from 8 a.m. to 6 p.m. On-site hardware service by IBM or CompuSystems technicians. And the capability to link our computer to yours for the fastest possible diagnosis and solution.

Electronic claims filing with N.C.'s major carriers

Most physicians know that electronic claims filing delivers faster turnaround and better cash flow than manual filing. Electronic filing also reduces errors, staff time, and stress.

That's why we offer electronic filing to North Carolina Blue Cross/Blue Shield, Medicare (Equicor), and Medicaid — features even some North Carolina-based vendors don't have. You can also transmit to the 30 leading carriers of the National Electronic Information Corporation (Aetna, The Travelers, New York Life and others) that together represent 80% of the commercial insurance market.

Here today, here tomorrow

The company was founded in 1976 by an engineer whose grandfather, father, and brother were all physicians. Since our first system, we've grown to serve over 1,200 physicians in more than 550 practices. (In S.C., we're the choice of more physicians than all our competitors *combined*.)

Our sole purpose is "Working for Physicians." We're not part of a large corporation distracted with other businesses, nor are we a garage operation learning the ropes at your expense. Instead, we have 15 years of successful experience and an ongoing commitment to you and your practice.

See the big picture

So for an insurance processing and billing system you can smile about, call us now at 1-800-800-6472. We'll answer your questions and help you decide on a configuration that suits your needs.



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